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IN THE

Supreme Court of the United States

OCTOBER TERM, 1968

No. 1019

CHAS. PFIZER & CO., INC.,
Petitioner,

v.

FEDERAL TRADE COMMISSION.

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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APPENDIX TO
PETITION FOR CERTIORARI

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United States of America

BEFORE FEDERAL TRADE COMMISSION

COMMISSIONER:

Paul Rand Dixon, Chairman
Sigurd Anderson
Philip Elman
Everette MacIntyre
A. Leon Higginbotham, Jr.

In the Matter of AMERICAN CYANAMID COMPANY, a corporation; BRISTOL-MYERS COMPANY, a corporation; BRISTOL LABORATORIES, INC., a corporation; CHAS. PFIZER & CO., INC., a corporation; OLIN MATHIESON CHEMICAL CORPORATION, a corporation; and THE UPJOHN COMPANY, a corporation	DOCKET NO. 7211

Opinion of the Commission

By Higginbotham, Commissioner:

The complaint in this matter charges respondents with unfair methods of competition and unfair acts and practices in commerce in violation of Section 5 of the Federal Trade Commission Act. The hearing examiner held in his initial decision that the evidence failed to establish that respondents had engaged in any of the violations alleged

in the complaint. The matter is now before the Commission on the appeal of counsel supporting the complaint from this decision.

In substance, the complaint alleges that Pfizer engaged in unfair methods of competition in the production and sale of antibiotics in that it unilaterally attempted to monopolize the antibiotics industry, attempted to and did monopolize the tetracycline industry, made false, misleading and incorrect statements for the purpose of inducing the United States Patent Office to grant a patent on tetracycline and caused said patent to be issued as a result of such misrepresentations; and independently thereof, caused the patent to issue although the product was unpatentable as a matter of law; and issued invalid licenses under said patent. The complaint further alleges that respondents by conspiracy fixed the prices of tetracycline, chlortetracycline (Aureomycin) and oxytetracycline (Terramycin); foreclosed and prevented competition in tetracycline and chlortetracycline by licenses and cross-licenses; attempted to and did monopolize tetracycline; Pfizer, Bristol and Cyanamid withheld material information from the Patent Office as a result of which Pfizer was enabled to secure the tetracycline patent; and Pfizer issued and Cyanamid, Bristol, Olin Mathieson Chemical Corporation (hereinafter referred to as Squibb), and Upjohn accepted licenses under the tetracycline patent with knowledge that material information was withheld from the Patent Office by at least one of the applicants for a tetracycline patent, and independently thereof, with knowledge the product was unpatentable.

Counsel supporting the complaint have taken exception to numerous findings and conclusions made by the hearing examiner with respect to the alleged agreements among respondents and with respect to the alleged misrepresentations to, and withholding of information from, the Patent

Office. They have not, however, argued that it is necessary that the Commission render a legal opinion as to the patentability of tetracycline.

I

Summary of Holdings

Shakespeare said "Brevity is the soul of wit".[1] Judging from the length of this opinion, and the separate findings of fact, some might infer that his admonition has gone unheeded. But here we are confronted with a record of over 11,000 pages, exhibits of approximately 8,000 pages, briefs totalling thousands of pages, and two full days of oral arguments on appeal before the Commission. Moreover, to some extent this opinion probes the arcane topic of antibiotic research. This antibiotic broth is spiced with the law of patents and unfair methods of competition. And so, out of a consideration for the rights of all the parties, we have set out in detail the breadth of their major contentions. However, for the sake of brevity, we are summarizing below our principal holdings which will be developed in greater detail in subsequent sections:

1. With respect to tetracycline this Commission is not passing on the issue of its patentability under the patent statutes and law. But this Commission holds that its jurisdiction extends to preventing the *enforcement* of a patent procured by unfair methods.

2. We hold that Pfizer by making certain representations and misrepresentations, and withholding other information, prevented the patent examiner from making an accurate appraisal of the patentability of tetracycline. Misrepresentations and the intentional withholding of material information to obtain a commercially valuable patent is

[1] Hamlet, Act II, Scene 2, Line 90.

an unfair method of competition and an unfair act or practice.

3. We hold that Pfizer engaged in such an unfair method of competition and unfair act or practice.

4. With respect to Cyanamid's and Pfizer's conduct before the Patent Office, there is evidence in the record which would allow us to draw the inference that Cyanamid and Pfizer conspired in the commission of this unfair method of competition. There is also evidence in the record from which a contrary inference may be drawn.

While "the possibility of drawing either of two inconsistent inferences from the evidence does not prevent the Commission from drawing one of them",[2] on balance as fact finders we neither exonerate Cyanamid and Pfizer nor do we find the case against them *on the issue of conspiracy before the Patent Office* proven by substantial, reliable and probative evidence, on the record as a whole. Thus the conspiracy charge before the Patent Office as to Cyanamid and Pfizer is simply "Not Proven".

5. However, as to the proceedings before the Patent Office, we hold that Cyanamid made misrepresentations to and withheld material information from the Patent Office. The type of information withheld was similar to that withheld by Pfizer. Thus, knowing the materiality of the information withheld, and knowing that this failure to reveal to the Patent Examiner would increase the probability of a patent issuing to someone, its receipt of a license under the Conover patent and the exercise of the rights granted thereunder, set the stage for the subsequent enactment of the price fixing conspiracy in which Cyanamid played a major role.

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[2] *Giant Food, Inc.* v. *Federal Trade Commission,* D. C. Cir., Slip Opinion, p. 14 (June 13, 1963).

6. We hold that Bristol did not engage in any unfair methods of competition before the Patent Office.

7. We hold that neither Squibb nor Upjohn engaged in any unfair methods of competition before the Patent Office.

8. We hold that Pfizer, Cyanamid, Bristol, Squibb and Upjohn engaged in a conspiracy to fix, maintain and stabilize the price of tetracycline.

9. Moreover, we hold that the totality of Pfizer's conduct amounts to a separate unfair method of competition, the basic purpose of which was to restrain trade in the sale and distribution of tetracycline. Its unfair conduct before the Patent Office set the stage for its subsequent actions and the later conspiracy of all the respondents. Moreover, its pricing practices aggravated and perpetuated the initial unfair method of competition. In sum, its conduct represents an unbroken chain of anti-competitive tactics which constitute a continuing unfair method of competition.

We are fully cognizant of the emphasis placed by the courts on the opportunity of hearing examiners to observe the demeanor of witnesses in order to appraise the credibility of their testimony. *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474 (1951). See also *FCC* v. *Allentown Broadcasting Corp.*, 349 U.S. 358, 364 (1955). However, our findings and conclusions on the question of misrepresentation and withholding information from the Patent Office are based on undisputed evidence and the testimony of expert witnesses. We feel it our duty, nevertheless, to set forth in detail exactly why the hearing examiner's reasoning and interpretation of the evidence cannot be accepted. And as to the price-fixing charge, we shall explain in detail our disagreement with the hearing examiner's interpretation of the record.

Opinion of the Commission

II

Scientific Background

This case involves the obtaining of a patent on tetracycline, one of the most important of the "broad spectrum" antibiotics. The annual sale of tetracycline has at least on one occasion exceeded the figure of one hundred million dollars. Besides tetracycline, the broad spectrum antibiotics include the following: chlortetracycline, sold under the name of Aureomycin; oxytetracycline, sold as Terramycin; and chloramphenicol, sold under the name of Chloromycetin. The earlier antibiotics such as penicillin and streptomycin are known as "narrow spectrum" antibiotics because they are normally effective against either gram-positive or gram-negative bacteria, but not both. "Broad spectrum" antibiotics are effective against both kinds of bacteria, as well as various other pathogenic organisms, and are for that reason commonly referred to as "the wonder drugs." Most of the antibiotics, including tetracycline, are fermentation products of particular microorganisms in aqueous nutrient media. The medium is inoculated with the microorganism and under controlled and aseptic conditions the microorganism is allowed to grow. The antibiotic or antibiotics produced are recovered, processed, and packaged in dosage forms. Tetracycline can also be produced by deschlorination of Aureomycin, *i.e.*, by subjecting Aureomycin to a process of mild catalytic hydrogenation to remove the chlorine atom from the Aureomycin molecule. This chemical transformation was the original method by which tetracycline was discovered.

Varios patents are held by respondents on the broad spectrum antibiotics. These patents cover not only the processes for making the antibiotic, but also the antibiotic product itself. If a patent is obtained on a basic antibiotic product, the patentee has the legal right to exclude all

others from making or selling this product and even from using this product in the manufacture of a completely different antibiotic. 35 U.S.C. Sec. 271 (a). The basic patents on the broad spectrum antibiotics are set forth in the following paragraphs. It should be emphasized that there are many related patents not mentioned covering improved processes and recovery methods.[3]

The patent covering Aureomycin is the Duggar patent issued to Cyanamid on September 13, 1949. The Niedercorn patent, issued September 2, 1952, to Cyanamid, is an improvement patent on the Duggar fermentation process. No company has been licensed to sell Aureomycin, although Bristol obtained a limited license from Cyanamid to produce Aureomycin in amounts up to 6% in the manufacture of tetracycline. This license was granted in settlement of a patent infringement suit commenced by Cyanamid against Bristol. Pfizer has a license to produce Aureomycin for the manufacture of tetracycline by the deschlorination method.

Pfizer owns the Sobin patent which covers both Terramycin and the fermentation process for making Terramycin. Pfizer has licensed no company to manufacture or sell this product.

Pfizer also owns the Conover patent on the product tetracycline and the deschlorination process for making it. As a result of a cross-licensing agreement negotiated by Pfizer and Cyanamid in settlement of an interference proceeding in the Patent Office, Cyanamid has a license under the Conover patent to manufacture and sell tetracycline. Bristol obtained a license to manufacture and sell tetracycline in setlement of an infringement suit filed by Pfizer. As part

[3] According to a tabulation contained in the F.T.C. Economic Report on Antibiotics Manufacture, June, 1958, p. 235, as of 1956, there were 14 United States patents relating to tetracycline, 16 patents relating to Aureomycin, 3 patents relating to Terramycin and 36 patents relating to Chloromycetin.

of the same settlement, Squibb and Upjohn obtained a license from Pfizer to sell tetracycline to the "drug trade."

Cyanamid's basic Aureomycin patents, the Duggar and Niedercorn patents, are in the record as Commission Exhibits 1 and 2. It is stated at the beginning of the disclosures of the Duggar patent that ". . . one of the objects of the present invention [is] to describe a new antibiotic substance which is highly effective against Gram negative bacteria. Not only is the new antibiotic of the present invention active against Gram negative organisms of a large number and wide variety, it is also active against many of the common pathogenic Gram positive bacteria. Accordingly, a further object of the invention is to provide a substance possessing bacteriostatic or bacteriocidal activity against pathogenic organisms of both the Gram positive and Gram negative groups."

The molecular structure of this "antibiotic substance" which Duggar called Aureomycin was not known at the time the Duggar patent was issued. Therefore, it was necessary to describe it by observed characteristics including certain chemical properties, the refractive indices of crystals, and characteristic spectroscopic absorption bands in the ultra violet and infra red ranges of the spectrum. Later research has shown that when following certain procedures, the resultant product is actually composed of two different antibiotics which are now technically referred to as chlortetracycline and tetracycline, with the tetracycline usually constituting something less than ten percent of the antibiotic substance. The Duggar patent goes on to describe the microorganism which was found to have produced Aureomycin, stating that it was isolated from a soil sample taken from a timothy field in Missouri and that a sample of the organism had been deposited with the Fermentation Division of the Northern Regional Research Laboratory at Peoria, Illinois, and given the identifying number of NRRL-2209. The Duggar patent states that this micro-

organism differs from any previously described species and proposes to name it *Streptomyces aureofaciens.* Then follows a description of a means of producing Aureomycin by growing a culture of *S. aureofaciens* in a nutrient medium under prescribed conditions of time, temperature, pH and other conditions. Duggar explains that various processes relying upon physical and chemical properties of Aureomycin may be devised for recovering it from the fermentation liquor and sets forth a recovery method that was described in another pending patent application. This recovery method is commonly referred to as the Pidacks Florisil-column recovery method.

Cyanamid's Niedercorn patent, as noted before, covers an improved fermentation process for making Aureomycin. This patent refers to the Duggar patent and states that:

> An object of this invention is to provide a process whereby the production of and yield of the antibiotic known as aureomycin may be improved. . . . It is a further object to produce a fermentation medium in which tap water may be used, in which a cation is introduced which will cause the aureomycin produced to be present in an insoluble form, and in which the pH is controlled or controllable within a range in which the yields are particularly satisfactory.

The patent further states that for maximum growth, it is necessary that the pH of the fermentation medium be controlled within rather narrow limits and that the pH of the fermentation must be stabilized. The patent then describes some 44 specific examples of media to be used with instructions as to how the fermentation should be conducted.

During 1952, a Pfizer research team of scientists ascertained the chemical structure of Aureomycin and Terramycin. Doctors L. H. Conover, C. R. Stephens, and R. B.

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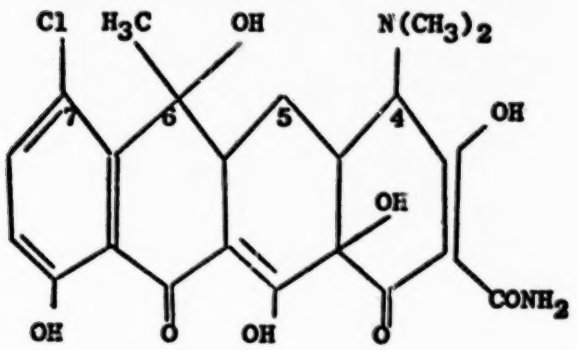
Woodward of Harvard University, among others, were members of this team. The structures of Aureomycin and Terramycin proved to be very similar. Both consisted of a group of 4-rings illustrated below, the difference being that Aureomycin at position 7 possessed a chlorine atom, but did not have a hydroxyl group at position 5. The converse was true in Terramycin, namely, a hydroxyl group appeared at position 5 whereas at position 7 there was no chlorine atom.

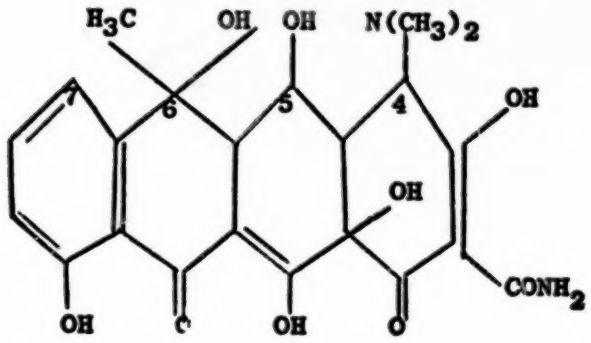
The structures of Aureomycin, Terramycin, and tetracycline are:

(See Opposite) ☞

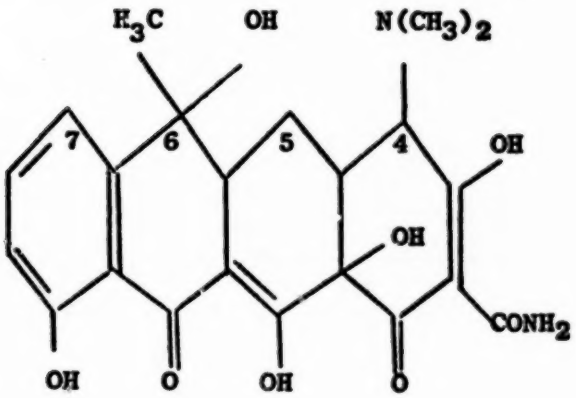
AUREOMYCIN
(CHLORTETRACYCLINE)



TERRAMYCIN
(OXYTETRACYCLINE)



TETRACYCLINE



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Dr. Conover speculated that it might be possible to develop an antibiotic by removing the chlorine atom from Aureomycin. He speculated that such an antibiotic might have qualities superior to Aureomycin and Terramycin. Dr. Conover succeeded in making this antibiotic in June of 1952 by hydrogenating Aureomycin, a process of replacing the chlorine atom with a hydrogen atom.

In October of 1952, an article (referred to herein as the "Stephens article") authored by the Pfizer research team was published by the *Journal of American Chemistry* disclosing the structures of Aureomycin, Terramycin, and tetracycline, although it was not disclosed how tetracycline could be made. In view of the similarity of the structures of these three compounds, Aureomycin and Terramycin were given the generic names of chlortetracycline and oxytetracycline.

III

TETRACYCLINE PATENT APPLICATIONS BY THE RESPONDENTS

A. *PFIZER* — On October 23, 1952, the Conover application for a patent on tetracycline and the deschlorination process was filed by Pfizer with the Patent Office. On July 23, 1953, the Patent Office rejected the product claims in the Conover application on the ground that the subject matter was obvious in the light of the Duggar and Sobin patents because of the similarity of the structural formula of tetracycline to Aureomycin and Terramycin. On October 20, 1953, Pfizer filed an amendment to its patent application pointing out that the structures of Aureomycin and Terramycin were not known at the time of Conover's discovery of tetracycline. Thereafter, the patent examiner, Lidoff, withdrew the aforementioned ground for rejecting the Conover claims.

Pfizer entered the race for a patent on the fermentation process by filing the Tanner application on November 12,

1953. Tanner alleged in the application that a new strain of Streptomyces, unidentified as to species, was used in the process.

B. *CYANAMID* — As a result of the indication in the Stephens article of the probable existence of tetracycline and its structure, other companies began experimenting and discovering ways of making it. On March 16, 1953, Cyanamid filed its Boothe-Morton application for a patent on tetracycline and a process for manufacturing it by deschlorination of Aureomycin.

Cyanamid scientists were also at work on a fermentation process and discovered that it could be made by using certain strains of *S. aureofaciens* with the use of a medium with a low chloride ion concentration. On October 15, 1953, Cyanamid filed its Martin-Bohonos application for a tetracycline fermentation process.

C. *HEYDEN* — On May 23, 1953, Dr. Minieri of the Heyden Chemical Corporation produced tetracycline by fermentation and filed application for a patent on September 28, 1953. This was apparently the first discovery that tetracycline could be made by direct fermentation. The application stated that the process used a newly discovered microorganism and mutants thereof and that the fermentation media were substantially free of chlorides. On October 1, 1953, Heyden publicly announced its discovery.

On October 27, 1953, Minieri's attorney filed a request for an interference on tetracycline, stating that he had reason to believe that there were two other similar applications pending. On October 29, 1953, patent examiner Lidoff rejected process claims in the Minieri application as lacking invention over the Duggar fermentation process. He stated:

> The production of tetracycline as well as varying amounts of aureomycin (chlortetracycline) would ap-

pear to be inherent in the process of Duggar, whose claims are not restricted solely to the production of aureomycin (chlortetracycline). There is found no patentable invention in culturing Duggar's mutants under the same conditions and finding that tetracycline as well as chlortetracycline is produced.

The product claims were rejected on the basis of the Stephens article which had described the structure of tetracycline before the date of Minieri's application. Examiner Lidoff notified Minieri that to be entitled to a product claim for interference purposes, Minieri would have to show that his discovery was made before the date of the Stephens article. At the same time, Lidoff issued notices to Pfizer (Conover) and Cyanamid (Boothe-Morton) to copy claims for a proposed interference on tetracycline and the deschlorination process.

Early in November, Cyanamid acquired the Minieri application along with its purchase of Heyden's Antibiotic Division. Harvey Edelblute, Cyanamid house counsel, eventually became the attorney handling the Minieri application. On November 16, 1953, Edelblute had an interview with Lidoff who inquired about the possibility that tetracycline may have always been concomitantly produced by Cyanamid in its production of Aureomycin. Edelblute filed a statement in December 1953, assuring the examiner that Cyanamid had investigated the matter and had determined that coproduction did not occur. Later in December a Cyanamid scientist ascertained that commercial Aureomycin contained some tetracycline. (CX 81)

D. *BRISTOL* — Bristol in the meantime had discovered that earlier experimental fermentation work it had done, which had been abandoned, probably produced tetracycline and on October 19, 1953, Bristol filed the Heinemann

application for a patent on the product tetracycline and on a fermentation process. Heinemann described the microorganism used as a new species of microorganism and tentatively called it Streptomyces BL 567201.

On December 8, Lidoff rejected both the process and product claims in Bristol's Heinemann application on the assumption that inherent production of tetracycline occurred in the Duggar and Niedercorn processes, in which case tetracycline and the Heinemann fermentation process would lack novelty and could not be patented. He ruled:

> Claims 8 to 17 are rejected as lacking invention over each of Duggar and Niedercorn, particularly when considered in the light of the J.A.C.A. publication. Each of these patentees shows a process of producing a mixture of antibiotics having the same basic formula as that proposed by applicant, which comprises growing a Streptomycete and mutants thereof under controlled conditions. Applicant's species may be a mutant of the species used by patentees. It is recognized that different mutants produce different proportions of the tetracycline antibiotic, depending in part upon strain and upon media. The media of both applicants and patentees comprise a nitrogenous and carbohydrate containing aqueous solution. Culture is carried out under submerged aerobic conditions until substantial antibiotic activity is imparted to said solution, and the antibiotic is recovered from the broth. The temperature and duration of the fermentation of both patentees and applicants come within the same range. Neither the private collection number of the organism nor the arbitrary name assigned to the product serve to distinguish patentability over the process of patentees. Product claims 1 to 7, 18 to 20 are similarly rejected as being unpatentable over each of Duggar and Niedercorn since it appears, from the processes thereof, that

applicant's product must be produced inherently. The claims read on the product in any environment (see In re Kebrich 671 O.G. 597 and Parke, Davis v. Mulford, 189 F. 95).[4]

A similar statement as to inherent production was made a few days later when the same patent examiner rejected the process claims in Cyanamid's Martin-Bohonos application.

On January 15, 1954, Bristol divided out some of its claims in the Heinemann application and placed them in continuation-in-part applications. One of these applications contained claims for tetracycline salts, and an affidavit by a Bristol scientist filed with the application contained statements to the effect that the salts had unexpected qualities over the free base. The purpose of the affidavit was to support Heinemann's contention that the description of the free base in the Stephens article would not bar a claim for certain salts such as tetracycline hydrochloride.

On February 8, 1954, the examiner rejected the process claims in Heinemann's continuation-in-part application as being unpatentable over the analogous processes of Duggar, Niedercorn, and Sobin. No mention was made, however, that the examiner based this rejection on the ground that tetracycline was coproduced in these fermentations. He also notified Heinemann that he proposed to declare an interference on tetracycline hydrochloride.

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[4] Commission Exhibit 9, p. 31. The product claims were also rejected on the ground that the Stephens article constituted a statutory bar, since under 35 U.S.C. 102(b) it was published more than one year before the date of Heinemann's application.

IV

The First Interference

On December 28, 1953, Lidoff declared an interference (referred to herein as the "first interference") on tetracycline and the deschlorination process. The interference was between Pfizer's Conover application and Cyanamid's Boothe-Morton application. Pfizer and Cyanamid entered into an agreement looking toward an amicable settlement of this interference. The parties agreed to exchange proofs as to priority of invention of tetracycline. The agreement further provided for cross-licensing of all patents covering tetracycline and its preparation by the deschlorination process regardless of which party secured the patent. After an exchange of evidence, Cyanamid conceded priority to Pfizer in February of 1954 and the interference was terminated. At the same time Cyanamid licensed Pfizer to produce Aureomycin for the manufacture of tetracycline.

V

The Second Interference

On March 2, 1954, Examiner Lidoff declared an interference on tetracycline hydrochloride between Cyanamid's Minieri application, Bristol's Heinemann application, and Pfizer's Conover application. This declaration constituted a tentative determination that tetracycline hydrochloride was patentable. Several motions were filed by all parties, including a motion by Pfizer to dissolve the interference on the ground that the others did not have a valid claim for tetracycline hydrochloride. Cyanamid moved to dissolve the interference on the ground that tetracycline hydrochloride was not patentably distinct over the disclosures of the Stephens article. During the second interference, numerous briefs and motions were filed that are not particularly pertinent to the issues of this case. In the

course of this interference, however, Edelblute denied on at least two occasions that tetracycline was inherently produced in the Duggar or Niedercorn processes. Thus, on June 14, 1954, in conjunction with a motion to add fermentation counts to the interference, Edelblute stated:

> Insofar as the prior art is concerned, none of Duggar, Sobin et al. or Niedercorn show that tetracycline can be produced by fermentation with the use of tetracycline elaborating strains of *Streptomyces.* This result is not inherent and as the discovery represents a major advance in the art, the claims directed thereto are believed to be patentable. (Comm. Ex. 12, p. 36)

In another paper filed with the examiner on August 23, 1954, Edelblute stated: ". . . there is no evidence that tetracycline was inherently produced by the prior art processes of Duggar, Niedercorn, Sobin, or others." (Comm. Ex. 12, p. 383)

During the second interference Bristol filed various motions to delay the final determination of priority. Bristol commenced selling tetracycline under its own trade mark in May, 1954, and entered into agreements with Squibb and Upjohn in September, 1954, whereby Bristol was to supply Squibb and Upjohn with bulk tetracycline. Both Pfizer and Cyanamid opposed Bristol's efforts to delay the interference proceedings. On July 19, 1954, in opposition to Bristol's motion for postponement of hearing, Edelblute stated:

> It does not appear that any unreasonable hardship or irreparable injury to the party Heinemann et al. will result if the motion is denied, but on the contrary, grave injury to the commercial position of the other applicants with respect to the product in issue will occur if this proceeding is delayed by the extension of time requested. It is, therefore, submitted that the

motion for postponement should be denied. (Comm. Ex. 12, p. 93)

Pfizer filed an affidavit, signed by Vice President John L. Davenport, stating that Pfizer was losing $50,000 a month in royalties from Cyanamid because of delay in the issuance of the tetracycline patent to Conover. In a subsequent paper filed with respect to Bristol's argument that Cyanamid therefore had no reason for opposing postponement, Cyanamid's counsel responded:

> Cyanamid would rather pay royalties to a bona fide patentee than see the pharmaceutical business in which it has a major interest ruined by irresponsible price cutting. (Comm. Ex. 12, p. 115)

On October 14, 1954, Lidoff ruled on the various motions filed by the parties. He reversed his former ruling that tetracycline hydrochloride was patentably distinct over the base. This necessitated termination of the interference since it barred Heinemann's claim for the salt, and Minieri was estopped from claiming the salt because its assignee (Cyanamid) had conceded priority to Pfizer on tetracycline in a previous interference. On his own motion, Lidoff ruled that tetracycline and its hydrochloride were unpatentable as to all parties for an independent reason. The examiner's ruling on this point is set out below:

> The interference count is unpatentable over the disclosures of Duggar U.S. 2,482,055, Sep't 13, 1949 and Niedercorn U.S. 2,609,329, Sep't 2, 1952, and the interference is dissolved. Duggar and Niedercorn each produce an antibiotic, disclosed as "Aureomycin" by a fermentation process employing *Streptomyces aureofaciens* and mutants thereof. The antibiotic is identified as an antibiotic by assay against bacteria. It appears from the disclosure of Minieri et al (a party to

this interference in an application available to all the parties) that tetracycline is *also* produced in such a fermentation process and that larger proportions thereof are produced when the amount of chloride in the fermentation medium is low . . . Minieri et al clearly and specifically disclose that the microorganism used to prepare *tetracycline* belongs to the Duggar et al U.S. 2,482,055 species and that "the characteristics are identical with those exhibited by a known culture of *S. aureofaciens*". While neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate, and disclose, that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes (see In Re Lieser 1947 C.D. 447; and Allen et al v. Coe 1943 C.D. 55). It has long been held that a purer form of an old product is not invention and the (apparent) mixture of the prior art meets the count (see Parke-Davis v. Mulford 189 F. 95 and In Re Kebrich 96 US PQ 411). (Emphasis in original.)

The interference was dissolved and on November 24, 1954, the applications were individually rejected (as to their product claims) for the same reason.

The chronological history of the various applications before the Patent Office is outlined in the following chart:

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PROGRESS OF APPLICATIONS BEFORE THE PATENT OFFICE

	October 1953	*November 1953*	*December 1953*	*January 1954*
Conover Application (Pfizer) Parent application filed Oct. 23, 1952 for tetracycline and deschlorination process.	October 29, patent examiner issues notice to copy process claim for proposed interference on tetracycline and deschlorination process.	New claim added as suggested.	December 28, patent examiner declares the first interference (between Conover and Boothe-Morton).	Exchange of proofs between Pfizer and Cyanamid. Cyanamid conceds priority to Pfizer.
Boothe-Morton (Cyanamid) Application filed March 16, 1953, for tetracycline and deschlorination process.	October 29, patent examiner issues notice to copy claims for proposed interference.	New claims added. November 16, Edelblute has interview with examiner who inquires about inherent production.	Statement filed by Edelblute (received on December 7) denying coproduction. December 28, first interference declared.	
Minieri (Heyden-Cyanamid) Application filed September 28, 1953, for tetracycline and fermentation process.	October 29, process claim rejected on basis of inherent production in Duggar patent. Notice of proposed interference.	November 4, Cyanamid purchases Minieri application.	December 14, Edelblute appointed attorney.	
Martin-Bohonos (Cyanamid) Application filed October 15, 1953, for tetracycline and fermentation process.			December 11, patent examiner rejects process claims as unpatentable over Duggar & Niedercorn.	
Heinemann (Bristol) Application filed October 19, 1953, for tetracycline and fermentation process.			December 8, patent examiner rejects both process and product claims on the assumption of inherent production in Duggar & Niedercorn.	January 15, continuation-in-part application filed on tetracycline salt and process. Affidavit filed alleging the hydrochloride to have unexpected qualities over the base.
Tanner (Pfizer) Application filed November 12, 1953, for fermentation process.	(No office action until July 1954)			

PROGRESS OF APPLICATIONS BEFORE THE PATENT OFFICE

November 1953	*December 1953*	*January 1954*	*February 1954*	*March—September 1954*
ew claim added as suggested.	December 28, patent examiner declares the first interference (between Conover and Boothe-Morton).	Exchange of proofs between Pfizer and Cyanamid. Cyanamid concedes priority to Pfizer.		March 2, patent examiner declares second interference on tetracycline hydrochloride. Numerous motions filed by all three parties. Pfizer seeks termination of interference and files affidavit that it is losing $50,000 a month in royalties because of delay.
ew claims added. November 16, delblute has interview with examer who inquires about inherent roduction.	Statement filed by Edelblute (received on December 7) denying coproduction. December 28, first interference declared.		February 12, patent examiner rejects claims as a result of the concession by Cyanamid in the first interference. Application eventually abandoned.	
lovember 4, Cyanamid purchases Tinieri application.	December 14, Edelblute appointed attorney.		February 19, patent examiner suggests for purposes of an interference a claim for tetracycline hydrochloride. (Claim was added.)	Second interference declared. Cyanamid seeks to persuade examiner to dissolve interference on the ground that tetracycline hydrochloride is not patentably distinct over the base. Edelblute again denies that tetracycline was inherently produced in prior art.
	December 11, patent examiner rejects process claims as unpatentable over Duggar & Niedercorn.			
	December 8, patent examiner rejects both process and product claims on the assumption of inherent production in Duggar & Niedercorn.	January 15, continuation-in-part application filed on tetracycline salts and process. Affidavit filed alleging the hydrochloride to have unexpected qualities over the base.	February 3, counsel files argument that Duggar & Niedercorn are not prior art against applicant's claims. February 8, patent examiner rejects process claims as unpatentable over Duggar & Niedercorn & Sobin patents. Suggests tetra. hydrochloride for interference. No mention of a speculation of inherent production.	Second interference declared as to continuation application. Parent application rejected on basis of Stephens article. No rejection on basis of inherent production. Bristol seeks to delay second interference by dilatory tactics.
				July 20, patent office rejects process claims on inherent production.

November 1954	*December 1954*	*1955*	
November 24, patent examiner rejects product claims in ex parte proceeding on basis of inherent production in Duggar & Niedercorn. November 29, conference with patent examiner.	December 8, Tanner & Bogert affidavits filed. December 9, supplemental affidavit filed. Patent examiner allows claims.	January 11, patent issued. Pfizer files infringement action against Bristol, Squibb, and Upjohn.	
November 24, ex parte rejection of product claims on basis of inherent production.		Cyanamid eventually receives patent No. 2,734,018, on process claims as an improvement patent over Duggar & Niedercorn.	
November 24, ex parte rejection of product claims on basis of inherent production.	Heinemann begins tests to prove that tetracycline is present in the production of aureomycin.	January 5, patent office division receives Taylor affidavit. January 21, another Heinemann application rejected over Duggar & Niedercorn.	Bristol abandons product claims in all applications.
November 2, patent examiner rejects claims as unpatentable over a prior art process. Patent examiner speculates that Duggar process inherently produces tetracycline.			May 4, Hutz argues that tetracycline was not an impurity in Duggar fermentation. "Patent office is now aware that inherent production is not in fact true."
		January 20, Hutz states that tetracycline was first produced by deschlorination.	

VI

The Conover Ex Parte Application

On October 15, 1954, one day after the disposition of the second interference, Dr. Murphy, a former Pfizer research chemist who was then employed by Pfizer as a patent agent, issued memoranda to two Pfizer scientists, Dr. Fred Tanner and Dr. Virgil Bogert, instructing them to conduct work on the question of co-production of tetracycline with NRRL-2209, and strain of *S. aurcofaciens* which had been deposited by Cyanamid in the public culture collection of the Northern Regional Research Laboratory maintained by the Federal Government. It was made clear to these scientists that the work was in connection with the prosecution of the Conover application and that the results might be used in preparing affidavits for the Patent Office. Tanner was instructed to summarize all fermentation work that had been conducted to that date with NRRL-2209, "particularly with respect to the proportion of Aureomycin and tetracycline produced in media specifically described or generally disclosed in the Duggar and Niedercorn Aureomycin patents." He was also instructed to conduct fermentation with NRRL-2209 in accordance with the examples set forth in the Duggar and Niedercorn patents and to have each fermentation broth checked for total broad spectrum antibiotic potency. Bogert, in turn, was instructed to recover and purify by the Pidacks Florisil-column method (the method of recovery referred to in the Duggar patent) the antibiotics present in the fermentation broths prepared by Tanner and to determine the total broad spectrum potency. He was also told to determine the Aureomycin and tetracycline content of the recovered products. In connection with the latter instruction, Murphy stated, "This presumably will be determined primarily by paper chromatography tests. However, if other methods are available for determination of this ratio, these should also be utilized." (CX, 55, 57, 66)

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The Pidacks Florisil-column procedure, a column chromatography procedure disclosed in the Duggar patent as a method of recovering Aureomycin from a fermentation broth, involves a process by which the filtered fermentation liquor is passed through a column filled with a substance to which the antibiotics adhere as the broth passes over it. The column is then "eluted" (washed out) with a proper solvent. As the solvent, containing both antibiotics and impurities, comes out of the column, it is segregated in portions called "bands" or "fractions". Dr. Bogert, in a test run on a Niedercorn broth in November 1954, determined that most of the tetracycline present is destroyed when one strictly follows the Pidacks' procedure, but that the result could be obviated by a slight modification of the procedure. (CX 59, 60; Tr. 4413; CX 58-c)

Paper chromatography is a method that can be used for identifying tetracycline and many other substances. It consists of placing a spot of the material being examined on a strip or sheet of filter paper and allowing a solvent to flow over the paper by capillary action. The paper is removed from the solvent, immobilizing spots of the material which have migrated. Previous tests have established that tetracycline and other products have certain characteristics in the rate at which they migrate. The results of the paper chromatography can be compared against these standards. In the case of an antibiotic such as tetracycline, the spots can be identified by placing the sheet or strip on a seeded agar plate which will reveal the presence of antibiotic substances. Paper chromatography can be used to determine the percentages of tetracycline present by measuring the zone of inhibition of the bacteria test organism present in the agar medium.

The *Craig countercurrent separation procedure is a method which can be used to separate tetracycline from Aureomycin.* It is based on the manner in which a substance will distribute itself between two immiscible sol-

vents. Two substances which have different distribution coefficients, such as tetracycline and Aureomycin, can be separated by this method.

On October 19, 1954, Werner H. Hutz, Pfizer's outside patent counsel handling the Conover application, wrote a letter to Murphy expressing great interest in the results of the experiments (CX 1027). Notwithstanding this expressed interest, he testified during the hearing that, within two days of this date, he had ordered the work stopped because it occurred to him that he did not know the information the patent examiner would require to overcome the rejection of Pfizer's patent claims. (Tr. 3913) According to Bogert, Dr. Murphy requested him "not to do any more work or make any more entries" in his official notebook. (CX 37, p. 20) The record shows that Bogert continued the tests but recorded the results outside his regular records. (CX 58)

Pursuant to the original instructions given by Murphy, Dr. Tanner prepared several broths, among which were two broths prepared in accordance with the specifications set forth in Niedercorn Example I. One of these broths had a bio-assay potency of 75 micrograms per milliliter (calculated as Aureomycin). Bogert applied a modified Pidacks procedure to this broth and obtained a number of fractions which were found by paper chromatography to contain tetracycline. Bogert testified that these tests showed tetracycline to be present and to be present in quantities "not more than five per cent." (Tr. 4412) Bogert did not attempt to isolate the tetracycline. The Commission has found on the basis of expert testimony that tetracycline could have been recovered from these fractions as of October 1954 by the Craig countercurrent separation procedure. (Tr. 2826, Tr. 11,032; 11,043-11,045)

On November 29, 1954, Hutz and Murphy conferred with the patent examiner. In accordance with Patent Office practice, a summary of what transpired at this conference

was drafted and filed by Hutz at the next conference on December 8, 1954. This summary[5] shows that Hutz and Murphy argued to the examiner that there was no reasonable basis for his speculation as to coproduction of tetracycline in the prior art processes and that "The available evidence is overwhelmingly contrary to the Examiner's assumption." The patent examiner informed Pfizer's representatives that he would withdraw his rejection of Pfizer's tetracycline product claims if Pfizer could demonstrate that tetracycline could not be recovered in clearly identifiable form from fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the strain *S. aureofaciens* NRRL-2209 which had been deposited by Cyanamid with the Northern Regional Research Laboratory as part of its disclosure requirements in receiving the Duggar patent.

The Niedercorn patent contained a large number of examples of media, however, and Pfizer used Example 28. Hutz testified that the examiner selected this example himself and required Pfizer to use it because it appeared to contain only a trace of chloride ion. It is evident, however, that the examiner was interested in the possible production of tetracycline in any of the Niedercorn examples. The Pfizer representatives did not disclose that Bogert had previously found that NRRL-2209 fermented in the medium described in Example I of Niedercorn, produced a broth of 70 micrograms per milliliter, and that using a modified Pidacks method and paper chromatography he had found approximately 5 per cent of the filtered broth to consist of tetracycline.

Furthermore, in September of 1954, two months earlier, Tanner, as part of a general research project to determine the production of tetracycline by various means of fermentation, had fermented NRRL-2209 in a Niedercorn 28

[5] The summary is set forth in the Findings at p. 24.

medium and had found the resulting broths to be less than 10 micrograms per milliliter. *These broths were so poor in antibiotic potency that they were classified as containing no Aureomycin or tetracycline.* These findings, which were relevant to the patent examiner's determination of which examples in Niedercorn to use, were not disclosed to him. When Tanner prepared the affidavit-test broths, the Niedercorn Example 28 had approximately the same low level of potency as the similar broths prepared by Tanner in September.

After the oral interview of November 29, 1954, Murphy immediately notified Tanner and Bogert that tests were to be conducted for the Patent Office to determine whether tetracycline could be recovered from Duggar and Niedercorn Example 28 broths using the three recovery procedures described in the Bogert-Welsh, Minieri, and Heinemann applications. Tanner prepared two broths—one as representative of the example set forth in the Duggar specifications and one as representative of the Niedercorn Example 28 broth. These broths were respectively designated as broths 1771A & 1771B. When these broths were turned over to Bogert, both biological and chemical assays were made by other Pfizer technicians at the request of Bogert. The potency of 1771B was assayed at 5.2 micrograms per milliliter (as Aureomycin) (14.3 by chemical assay). The record establishes that for low potency broths, the biological assays are more accurate. These potency figures were unusually low in comparison to the potencies set forth in the Niedercorn patent. (No potency figures were disclosed in Duggar.) Although Niedercorn did not specify the microorganism used, Example 28 discloses that a broth potency of 274 micrograms of Aureomycin per milliliter was obtained. Other examples set forth in Niedercorn show potencies ranging from approximately 100 to 400 micrograms per milliliter.

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Notwithstanding the low potencies of the test broths, the papers filed by Pfizer with the examiner indicated that these broths were "representative" of the Duggar and Niedercorn broths. The potency figures were not set forth or otherwise indicated. Expert testimony establishes that there is no way that Lidoff could have calculated the potencies of the test broths from the data contained in the affidavits. (Tr. 1912, 2869) The record also clearly establishes that the low potencies of the broths were a crucial factor in Pfizer's failure to recover tetracycline. (Tr. 1983-84, 4439) Under these circumstances, the statement that the broths were "representative" of the Duggar and Niedercorn broths was clearly misleading.

In this connection, the affidavit prepared by Tanner omitted a fact that may have been material to the patent examiner's determination of whether Niedercorn Example 28 was sufficiently duplicated. In his affidavit, Tanner indicated that the entire forty-hour fermentation (tank fermentation) was conducted in a medium having a pH value of 6.7. The Niedercorn patent states that for maximum growth it is necessary that the pH of the fermentation medium be controlled within rather narrow limits and that "Highly effective growths may be obtained within the range of about 5.0 to 8.0. Best results are obtained within the range of approximately 6.4 to 7."

In fact, Tanner's laboratory notes (CX 61) show that the medium was initially adjusted to 6.8 (which was recorded in the affidavit as 6.7), but after sterilizing the medium preparatory to inoculation, he found the pH to be 8.1. Without further adjustment of the pH, Tanner inoculated the medium and began the fermentation with the pH at 8.1. Six and one-half hours later Tanner returned to the laboratory and found the pH still tested at

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8.1. Tanner then adjusted the medium with sulphuric acid to bring down the pH value. During this six and one-half hour period, it was observed that no growth of the organism occurred. These facts were not disclosed to the patent examiner. Instead, the affidavit clearly conveys the false impression that the pH was constantly kept within the optimum range.

The two test broths prepared by Tanner were turned over to Bogert for recovery work. As noted before, Bogert had these broths assayed by both biological assay and chemical assay methods. Although the assays showed the broths to have little antibiotic content, Bogert proceeded to apply three commercial recovery procedures which were designed for direct recovery of tetracycline from higher potency broths. For example, one procedure was to be applied to a broth containing at least 100 micrograms per milliliter of tetracycline. The test broths used by Bogert, however, had only 5 to 7 micrograms of tetracycline and Aureomycin combined. Nevertheless, Murphy and Hutz represented that the techniques used were the best procedures designed for recovering any tetracycline present in the test broths.

In fact, other procedures were available which were more suitable for recovering tetracycline from low potency broths where the percentage of tetracycline approximates 5 to 10 per cent of the antibiotic material. These procedures were the column chromatography method and the Craig countercurrent distribution method. The latter method could have been used in conjunction with column chromatography or with the Bogert-Walsh recovery method. (Tr. 11,031-033, 11,042, 11052)

The record shows that Murphy and Hutz knew that the examiner was under the impression that the Pidacks Florisil-column chromatography method was suitable only for obtaining *Aureomycin* fractions from fermentation broths. Before representing to the examiner that the pro-

cedures used were the best available, they were under a duty to ascertain from Pfizer scientists what procedures were available. The record shows that earlier in November Bogert had successfully applied a modified Pidacks method to broths containing tetracycline. The record shows that Murphy instructed Bogert to use only the three procedures described in the Bogert-Walsh, Minieri, and Heinemann applications. (Tr. 4273)

Bogert's affidavit describes in detail the recovery techniques he applied. A few amorphous products were recovered, all having a low antibiotic content. As to the amorphous product obtained by the procedure taken from the Bogert-Walsh patent application, Bogert stated:

> This product was tested in a manner that he knows is capable of detecting even a small proportion of tetracycline in the presence of chlortetracycline and showed only chlortetracycline.

The Tanner-Bogert affidavits were submitted by Hutz and Murphy to the examiner on December 8, 1954, together with their own "Remarks" summarizing their version of the November 29 conference and an amendment of seven new claims. After examining these papers, the examiner requested more information as to the possibility of recovering tetracycline. The next day, December 9, Hutz and Murphy conferred again with the examiner. They submitted a supplemental affidavit signed by Bogert. Bogert's supplemental affidavit recited that he had applied an acid color test which should show whether the amorphous product recovered from broth 1,71A by Procedure A contained 20 percent or more tetracycline. He concluded:

> Based on these results and on his experience with the results of a great many such tests on materials containing tetracycline, chlortetracycline and mixtures thereof, he is convinced that not nearly as much as

20% of the potency of the amorphous material could be due to the presence of tetracycline, in fact there was no indication whatever of the presence of tetracycline. Assuming that the maximum possible proportion of the total potency due to tetracycline is 10%, this means that the 0.36 grams of amorphous material cannot contain more than about 0.009 grams of tetracycline. He does not know of any method whereby any part of such a minute amount of tetracycline could be separated and recovered in clearly identifiable form from the amorphous material.

Bogert's affidavit further stated that in each instance in which amorphous material had been recovered, the amount was so small and the potency so low that he knew of no method whereby "any part of the minute amount of tetracycline conceivably present could be separated and recovered in a clearly identifiable form." On the assurances given in the aforementioned affidavits and remarks, the patent examiner on December 9, 1954, granted a notice of allowance to Pfizer and the tetracycline patent was issued to Pfizer on January 11, 1955.

Several months later, in May of 1955, Edelblute filed papers in Cyanamid's Minieri application in which he stated that recent investigations were made by Cyanamid of the Duggar fermentation using various strains of *S. aureofaciens.* and it was found that under certain conditions and when using some strains of *S. aureofaciens.* small amounts of tetracycline had been produced. He also stated that "reinvestigation" of samples of commercial Aureomycin showed from 1 to 2½ percent tetracycline. (CX 8, p. 81)

During the same month, however, in a Pfizer application for a process of recovering tetracycline from a fermentation broth, Hutz, Pfizer's patent attorney, stated that tetracycline had not existed in Duggar fermentations as

an impurity and that *"It is believed that the Patent Office is now aware that this 'inherent' production is not in fact true.* Tetracycline would most emphatically not be an 'impurity' in the prior art method as the Examiner believed at the time of his last office action herein, and applicants' process would not be inherently performed by the reference." (CX 13, p. 16) (Emphasis Added)

The Heinemann applications were eventually abandoned by Bristol whose attorneys took the position that tetracycline was unpatentable because Bristol tests showed that tetracycline had been coproduced with Aureomycin.

On the same day that Pfizer received a patent on tetracycline, it brought infringement suits against Bristol, Squibb and Upjohn, seeking damages and a restraining order preventing them from marketing tetracycline. (Squibb and Upjohn had been buying tetracycline from Bristol in bulk and selling it in dosage form to the drug trade for several months.) Bristol, Squibb and Upjohn brought actions in the Southern District of New York seeking declaratory judgments that they were not infringing any valid claim of Pfizer's patent. In their answers to the Pfizer complaint they claimed the Conover patent was invalid because, among other things, it had been allowed by the Patent Office under a mistake of fact induced by Pfizer and that the claims of the patent were unenforceable because of Pfizer's "unclean hands" arising from its misrepresentations of fact to the Patent Office in its prosecution of the application on which the patent was obtained. Throughout most of 1955, Bristol, Squibb and Upjohn took numerous depositions of Pfizer's officials and technical workers and subpoenaed documents from Pfizer. These depositions were introduced as evidence in this proceeding by complaint counsel and support the defenses referred to above. The suits were eventually settled with Bristol receiving a license to manufacture *and* sell tetracycline. Squibb and Upjohn received licenses to sell tetra-

cycline to the drug trade. The licensees were required to pay Pfizer a royalty of 3½ percent of net sales.

VII

Alleged Misrepresentations and Withholding of Information Before the Patent Office

The hearing examiner dismissed the above charge for the reason that any misstatements of fact or withholding that the record discloses pertains to matter which was immaterial to the Patent Office's determination of the validity of Conover's product claims.[6] We disagree. *We find that the hearing examiner's decision is based on a misunderstanding of the patent examiner's rulings on tetracycline.* The hearing examiner's entire decision on this phase of the case contains a series of deductions from certain erroneous assumptions. He assumes (erroneously) that the Patent Office examiner, Lidoff, dissolved the second interference and rejected the Conover (Pfizer) product claims on the speculation that tetracycline, as an inherent part of commercial Aureomycin products, had been in *public use or on sale* more than one year before the date of Conover's application.[7] From this, and from certain conclusions of law based on decisions that Lidoff never relied

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[6] During the trial of this case, counsel supporting the complaint attempted to show that Pfizer made false statements and withheld information as to (1) coproduction of tetracycline in Aureomycin fermentation processes, and (2) the state of knowledge of the structure of Aureomycin and Terramycin at the time of Conover's discovery of tetracycline. The hearing examiner found against counsel supporting the complaint on both charges. Counsel supporting the complaint have taken exception to his findings as to the first charge. Consequently, our review of the patent phase of this case will be confined to the first charge.

[7] The Patent Office, in accordance with its general policy of not allowing its examiners to testify as to applications they have reviewed, did not allow Lidoff to testify in this case.

upon, he reasons that Lidoff must have been interested only in whether tetracycline was present in the final commercial product of Aureomycin and whether it was present in "substantial quantities" so as to impart utility to that product. From this he reasons that Lidoff's motive in requiring Pfizer to run tests was to determine whether tetracycline was present in the broth in (again) "substantial quantities" so that such quantities could have been recovered along with Aureomycin. From this conclusion and from erroneous findings that Lidoff always knew of coproduction of tetracycline in smaller amounts (less than "substantial") in the prior art processes and that Pfizer "conceded" that tetracycline constituted ten percent of Aureomycin, he reasons that no *material* misrepresentations or withholding of information occurred because the evidence shows that tetracycline almost always constituted something less than ten percent of Aureomycin.

The Commission contrary to the above conclusions by the hearing examiner, finds that:

(1) The patent examiner did not reject Conover's product claims on the ground that tetracycline may have been in public use or on sale more than one yeare before the date of Conover's application, but rather his rejection was based on the ground that it appeared that tetracycline was inherently produced by the fermentation processes described in the Duggar and Niedercorn patents and for the reason of inherent production alone would be unpatentable.

(2) Nowhere in the documents before the patent office did respondents or the patent examiner even allude to the public use and sale theory.

(3) The patent examiner informed Pfizer that he would not allow tetracycline product claims unless Pfizer submitted affidavits in which Pfizer scientists swore they could

not recover tetracycline from broths representative of those described in the Duggar and Niedercorn patents.

(4) Pfizer submitted such affidavits and the examiner allowed the claims, thereby enabling Pfizer to obtain a patent on the product tetracycline.

(5) Pfizer deliberately made false and misleading statements regarding the affidavit tests and suppressed the fact that Pfizer had previously found that tetracycline was produced by one of these fermentation processes.

(6) The patent examiner did not previously know that inherent production occurred in any of these processes and was not told of this fact by Pfizer, nor did Pfizer concede that tetracycline constituted ten percent of Aureomycin (or any other percentage, for that matter).

(7) The false statements and information withheld were material to the patent examiner's determination of the patentability of tetracycline and were known by Pfizer to be material.

To come to any other conclusion would be to torture the English language and make semantics rather than facts the basis for our rulings.

Public Use and Sale: The theory of law that the hearing examiner imputes to the mind of the Patent Office examiner Lidoff is based on the assumption that Lidoff dissolved the second interference and rejected the Conover claims on the ground that tetracycline had been in *public use or sale.* After he cites 35 U.S.C. Sec. 102 of the Patent Code which includes in paragraph (b) the statutory bar against a patent for an invention that has been in public use or sale in the United States more than one year prior to the date of application, the hearing examiner reviews numerous decisions and states at page 108 of his decision:

> The cases clearly establish that the prior unknown existence of a product, subsequently discovered, in an-

> other product which has been in public sale or use, does not constitute a disclosure barring patentability within the meaning of the statute. The exception to this principle relied upon by Lidoff, hereinabove discussed . . . was when the product, although unknown, had been on sale as part of, and imparted the utility to, a known product. The discovery and isolation of such a new product possessing the same utility is not patentable because no benefit is conferred upon the public, which as a result of the public sale had the utility available even though the source of the utility was not known or disclosed.

The hearing examiner's characterization of the statutory grounds upon which Lidoff rejected the Conover product claims is unsupported by any evidence of record. The record clearly indicates that Lidoff, rather than basing his rejection on the ground that tetracycline may have imparted utility to a product in use or on sale, speculated that Conover had discovered a product which had already existed in a prior art fermentation process that was described in prior patents as producing an "antibiotic substance" and for this reason lacked novelty that could not be patented. Although Conover was the first to identify tetracycline and its chemical structure, Lidoff ruled that *identification* of a substance that was inherently produced by a known process did not constitute a patentable invention. The reference by Lidoff to the Duggar and Niedercorn patents was reference to prior art that corresponds to Section 102(e): "A person shall be entitled to a patent unless—(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent." See also 35 U.S.C. Sec. 102(f). To clarify this matter and show that the hearing examiner's conclusion is erroneous, it will be necessary to review the theoretical foundations of patent law, in particular the concept of

"prior art," and the practice of Patent Office examiners' references to prior art.

There are three basic requirements for a patent: invention, novelty, and utility. *Cuno Engineering Corporation* v. *Automatic Devices Corporation*, 314 U.S. 84, 90 (1941).[8]

Invention: The concept of invention is not defined by statute other than the statement in Section 100[9] that it is an "invention or discovery" and the provision in Section 103 (enacted in 1952) that a patent may not be obtained if the differences between the subject matter and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." Nearly all courts construing this provision have held that it does not change the standard for invention as applied by courts prior to its enactment in 1952.[10]

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[8] The requirement of utility is not reviewed herein as there is no issue as to the usefulness of tetracycline. The hearing examiner's referral to the concept of "new and different utility" relates to the question of novelty.

[9] Statutory references are to sections of Title 35 of the United States Code.

[10] See, e.g., *In re Krogman*, 223 F. 2d 497 (C.C.P.A. 1955); *Wasserman* v. *Burgess and Blacher Co.*, 217 F. 2d 402 (1st Cir., 1954); *Stanley Works* v. *Rockwell Mfg. Co.*, 203 F. 2d 846 (3rd Cir., 1953), *cert. denied* 346 U.S. 818 (1953); *General Motors Corp.* v. *Estate Stove Co.*, 203 F. 2d 912 (6th Cir., 1953), *cert. denied* 346 U.S. 822 (1953); *Helms Products* v. *Lake Shore Mfg. Co.*, 227 F. 2d 677 (7th Cir., 1955); *Caldwell* v. *Kirk Mfg. Co.*, 269 F. 2d 506 (8th Cir. 1959) *cert. denied* 361 U.S. 915 (1959).

Section 103 also contains a provision that "Patentability shall not be negatived by the manner in which invention was made." A remark in the *Cuno* case, *supra*, characterizing inventions as a "flash of creative genius" had been interpreted by some courts as a new standard for invention. The Reviser's note to Section 103 indicates that this provision was intended to overcome any such inference. Cf. *Lyon* v. *Bausch & Lomb Optical Co.*, 224 F. 2d 530, 537 (2nd Cir.,

This standard cannot be readily summarized as it is composed of various negative definitions of invention as applied to particular factual situations.

Novelty: After Section 101 states that an "invention" can be patented, it adds the phrase: ". . . subject to the conditions and requirements of this title." The next section includes the requirements concerning novelty (and loss of patent rights).

> *35 U.S.C. 102. Conditions for patentability*; novelty and loss of right to patent. A person shall be entitled to a patent unless—
>
> (a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
>
> (c) he has abandoned the invention, or
>
> (d) the invention was first patented or caused to be patented by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country or an application filed more than twelve months before the filing of the application in the United States, or
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

A careful reading of Sections 102(a) and 102(b) will show that the difference between them lies in the priority of invention and timely filing of an application. Section 102(b) applies to situations where not only another person's invention has been patented, described, or publicly used, or on sale more than one year prior to the date of application, but where the applicant's invention has been so used or sold.[11] Both these paragraphs and paragraph (e) overlap each other to some extent in the situations they cover. All paragraphs except (c), (d), and (f) would usually overlap the independent requirement that "invention" be established; that is, a failure to meet the standard for novelty under Section 102 because of prior public knowledge,[12] use by others in this country, prior patent, or description in a patent or printed publication, public use or sale in this country, would in nearly all instances fail to

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[11] The policy behind this provision is to encourage prompt filing and discourage attempts to extend the statutory monopoly. *Shaw* v. *Cooper*, 32 U.S. (7 Pet.) 292, 320 (1833).

[12] The requirement that the knowledge be "public" knowledge was added by judicial construction in *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 18-19 (1829).

meet the more rigorous standard for invention over the prior art.[13]

"Prior art" is a term which covers the state of public knowledge in a particular science or skill. Those references to patents and printed publications which are considered applicable for purposes of determining whether a discovery is novel and inventive constitute what is known in patent law as references to the prior art. A patent examiner, when rejecting a claim by citing prior art, does not usually need to cite the statutory ground for his rejection since in most instances the basis for the rejection is apparent from the language employed.[14] Patent Office examiners would rarely have occasion, it would seem, to reject an application on the ground of prior public use or sale, as their time is spent in searching the technical literature of the prior art.[15]

The Patent Examiner's Rejection Was Based on Section 102(e).

Section 102(e) creates a statutory bar when the applicant's claim was anticipated by a description in another party's patent, the application date of which was prior to the applicant's date of invention. The predecessor of this

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[13] Pfizer's product claims in the Conover application presented an instance where the applicant's discovery was not obvious to one skilled in the art and yet was not patentable if coproduction occurred since this would negate novelty. Lidoff asserted that if tetracycline existed in the prior art it could not be patented. An analogous situation is where the substance previously existed in nature. See, e.g., *In re King,* 107 F. 2d 618 (C.C.P.A. 1939).

[14] Patent Office Manual of Patent Examining Procedure, 3rd ed., Sec. 707.07 (d).

[15] *Id.* Sec. 901.06(a). Section 706.03(v) of the Manual of Patent Examining Procedure expressly provides for the rejection of claims on the ground of prior use or sale where "public use proceedings" have been instituted and have terminated with the finding that prior use or sale was established. Public use proceedings are special hearings instituted at the direction of the Commissioner. Patent Office

section was interpreted by the Supreme Court in *Alexander Milburn Co.* v. *Davis-Bournonville Co.*, 270 U.S. 390 (1926), to mean that the disclosures in the specifications of the patent can anticipate the applicant's claim even though the prior patent did not *claim* the anticipatory art disclosed therein.[16] Anticipation results even though the prior patentee may not have appreciated the significance of the disclosure.[17] An applicant may show the prior art patent to be inapplicable, if he can, by submitting affidavit and proof under Rule 132 of the Patent Office Rules.

Against this background of patent law and Patent Office procedure it becomes evident that Lidoff did not dissolve the second interference and reject the Conover product claims on the ground of prior public use and sale one year before the application. Lidoff's stated ground for finding tetracycline unpatentable was:

> The product claims are unpatentable over the disclosures of Duggar, U.S. 2,482,055, Sept. 13, 1949 and Niedercorn, U.S. 2,609,329, Sept. 2, 1952. Duggar and Niedercorn each produce an antibiotic, disclosed as "Aureomycin" by a fermentation process . . . It appears from the disclosure of Minieri, et al. (a party to Interference No. 86. 861) in an application available to all parties that tetracycline is also produced in such a fermentation process . . . While neither Duggar and Niedercorn may have realized that tetracycline was in fact produced, they did appreciate, and disclose that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes (see In re Lieser, 1947 C.D. 447 and Allen, et al.

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[16] Section 102(e) is the statutory enactment of the *Milburn* decision. See Reviser's Note to Section 102.

[17] *In re Lieser,* 162 F. 2d 224 (C.C.P.A. 1947); *Allen* v. *Coe,* 135 F. 2d 11 (D.C.Cir., 1943); *In re Gauerke,* 86 F. 2d 330 (C.C.P.A. 1936).

> v. Coe, 1943, C.D. 55). It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the claims (see Parke Davis v. Mulford, 189 F. 95 and In re Kebrich, 96 USPQ 411). (Emphasis in the original) (CX 12, pp. 443-4; CX 4, pp. 31-32)

There is no indication in the above rejection of any speculation that tetracycline would be unpatentable for the reason that it was in public use or sale more than one year before the date of application. Nevertheless, the hearing examiner reasons at page 47:

> The presence of tetracycline in the fermentation broths was not a prior public sale or use, since such broths were never in public use or sale. However, if the resultant product Aureomycin, having been sold since 1948, contained tetracycline, it could be argued that tetracycline had been in public use and sale . . .
>
> In his rejection and rulings on the second interference the examiner specifically referred to the disclosure of Minieri that tetracycline was also produced in the fermentation process and that larger proportions were produced under certain conditions. He pointed out that, while Duggar and Niedercorn did not realize that tetracycline was in fact produced, they did appreciate and disclose that the product was an antibiotic. It will be noted that he made specific reference to the product at this point. Counsel supporting the complaint failed to distinguish between inherent production in the broths and in the product, and contend that inherent production in the broth would constitute a bar to patentability. For the reasons pointed out above, this clearly is not correct.[18]

[18] In support of the above conclusion, the hearing examiner states that Lidoff already knew that tetracycline was coproduced in the prior art broths. This finding is erroneous and will be discussed later in this opinion.

On the contrary, there is no indication whatsoever that Lidoff was concerned with commercial Aureomycin products. The record clearly shows that Lidoff's rejection was based on the theory that the description in prior art patents of a process which is disclosed as producing antibiotic substance, part of which is tetracycline, constitutes an anticipation of any later product claims for tetracycline. Lidoff's reference to a "product" in the sentence "While neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate and disclose, that the product was an antibiotic" was obviously a reference to the antibiotic substance (called Aureomycin) produced by the fermentation process which Lidoff speculated was actually a mixture of tetracycline and chlortetracycline. This was not a reference to the final commercial Aureomycin *products* as the hearing examiner surmised.

The hearing examiner does not even consider the possible relevance of Section 102(e) to Lidoff's rejection and merely assumes it was based on prior use and sale. Indeed, it appears that not even counsel for respondents argued that this was the basis for the rejection. Pfizer has contended throughout that Lidoff knew that the microorganism he required Pfizer scientists to use for the affidavit tests was a microorganism that was unsuitable for commercial production of Aureomycin. Therefore, the "public use and sale" theory lacks support even under respondent Pfizer's interpretation of Lidoff's rulings.

The Hearing Examiner's View of the Law.

As seen from the foregoing, the hearing examiner erroneously finds that Lidoff was interested only in whether tetracycline was present in commercial Aureomycin products. From this and from certain conclusions of law, discussed in the following pages, the hearing examiner reasons that Lidoff must necessarily have been interested only in whether tetracycline was present in commercial products

in "substantial quantities" so as to impart utility to the commercial product.[19]

Although recognizing that the issue of misrepresentation to the Patent Office was a basic issue in this case, the hearing examiner himself ruled on the question of ultimate patentability of tetracycline. Thus, at page 82, he states:

> Because certain allegations depend upon the legal significance of inherent production on patentability, it becomes material to determine whether or not the coproduction demonstrated in the record constituted such prior knowledge or use, public sale or use, or the other statutory bars, as to render the discovery of tetracycline unpatentable . . . In short, with respect to inherent production, it becomes necessary to ascertain, first, what the Patent Office wanted to know about coproduction, and what was represented to and/or withheld from it with respect thereto, and, second, independently of any such representations or withholdings, whether or not the facts concerning coproduction establish lack of patentability.

Although some of the allegations in the complaint do allege nonpatentability of tetracycline, other allegations charge simply that the Conover patent was issued as a result of misrepresentations submitted to the Patent Office. As we shall discuss in another portion of this opinion, *the enforcement of a patent whose acquisition was attended by substantial false representations constitutes an unfair method of competition within the meaning of Section 5 of the Federal Trade Commission Act*, and it is not necessary that we make an independent determination as to the patentability of tetracycline, although in the course of our opinion it will be necessary to discuss the legal theory

[19] At page 57 of his decision, the hearing examiner appears to define "substantial quantities" as meaning quantities constituting fifty percent or more of the products.

adopted by the patent examiner who reviewed the Conover application. Whether tetracycline is or is not patentable is a question of law upon which opinions could differ. We hold the hearing examiner clearly erred in his findings regarding Lidoff's motive for having Pfizer run fermentation tests. It is evident from the hearing examiner's decision that he failed to keep distinct the difference between a question of fact and a question of law.

The hearing examiner, instead of first determining by the record the question of *fact*—what did the patent examiner, Lidoff, consider to be an anticipation of the Conover claim for "tetracycline"—examines various patent law decisions to determine whether tetracycline is patentable. He concludes that there is good authority for the argument that a court, having all the facts concerning the coproduction of tetracycline in the Duggar and Niedercorn processes, should, neverthless, rule that tetracycline is patentable. The hearing examiner cites and discusses at length various decisions (that were not relied upon by Lidoff) in support of his conclusion as to patentability of tetracycline. Those cases which Lidoff did cite[20] in rejecting tetracycline claims and in dissolving the second interference are not fully discussed by the hearing examiner, and are distinguished on the ground that they were cases involving process claims rather than product claims (a "distinction" which was meaningless for the purpose for which Lidoff cited them), and finally are dismissed as not being the "best examples" of what Lidoff could have cited. The hearing examiner in discussing the cases he considered more "in point" and coming to the conclusion that tetracycline is a patentable invention, states at page 85 of his decision:

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[20] *In re Lieser,* 162 F. 2d 224 (C.C.P.A. 1947); *Allen* v. *Coe,* 135 F. 2d 11 (D.C., Cir., 1943); *Parke-Davis & Company* v. *H.K. Mulford Co.,* 189 Fed. 95 (C.C. S.D. N.Y. 1911), aff'd 196 Fed. 496 (2d Cir., 1912); and *In re Kebrich,* 201 F. 2d 951 (C.C.P.A. 1953).

> It must be assumed, of course, and the record establishes, that Mr. Lidoff was completely familiar with the patent laws and decisions and applied the appropriate precedents to his reasoning and rulings.[21]

Thus, the hearing examiner conceives that there is one definite law as to anticipation by prior inherent production and that Lidoff must have applied it. The hearing examiner's conclusion as to the "true" law of inherent production is stated at page 90:

> In summary, if a product has been inherently produced in an old product, but this was unknown, undisclosed, and imparted no utility to the prior product, such inherent production does not bar patentability.

After only a brief discussion of three of the four cases that Lidoff cited in support of his rejection, the hearing examiner, as noted, dismisses them as not the best examples that Lidoff could have cited. In discussing the fourth case, *Parke-Davis* v. *Mulford*,[22] the hearing examiner fails to comprehend Lidoff's reason in citing that case.

The hearing examiner states at page 86 of his decision:

> Contrary to the contentions of counsel supporting the complaint, there are no cases which stand for the prop-

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[21] Two of the cases which the hearing examiner discusses at great length to prove his point, one of which he says goes even further in finding patentability than would be required in the case of tetracycline, are 1958 decisions. Lidoff in rejecting the Conover claims in 1954 could not have been familiar with these decisions even assuming they would now serve as precedents if tetracycline patentability was an issue. Furthermore, the record shows that the other decisions that are similar in their facts are decisions of which Lidoff was aware. They had been cited to him and discussed at length by Bristol several times during the second interference in connection with other issues. Lidoff obviously did not consider them controlling as to tetracycline.

[22] *Parke-Davis & Co.* v. *H.K. Mulford Co.*, 189 Fed. 95 (C.C. S.D. N.Y. 1911), aff'd 196 Fed. 496 (2d Cir., 1912).

> osition that a newly discovered product, which had existed unknown and undisclosed as part of a prior compound and which possesses a different utility from the prior compound, is not patentable.

This may be true, but it is clear that Lidoff did not consider that tetracycline in mixture and tetracycline isolated have different kinds of utility. Tetracycline in both forms is an antibiotic. Lidoff made this clear in his rejection, stating at one point:

> While neither Duggar and Niedercorn may have realized that tetracycline was in fact produced, they did appreciate and disclose that the product was an antibiotic.

Lidoff's remarks then make it clear that he did not consider a purer form of tetracycline to be of a different kind of utility. He stated:

> It has long been held that the purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the claim (see Parke, Davis v. Mulford . . . and In re Kebrich . . .)

The *Parke-Davis* case, decided in 1911 by Judge Learned Hand, announced the general rule that a purer form of an old product is not inventive, but found an exception to that rule in the case where extraction and purification created a product which has a new utility that is different in kind rather than merely different in degree. The hearing examiner assumes that Lidoff cited *Parke-Davis* for the exception rather than for the general rule. But it is apparent to us from Lidoff's language and from the fact that the case was cited in *rejecting* Conover's claims that this case was cited for the general rule therein. If Lidoff had cited the case for the exception to the rule, then the citation would make sense only if he were allowing Conover's claims.

Moreover, it is clear to us that *Parke-Davis* was cited for another, but related, rule of law—that a claim for "tetracycline" (a broad claim) would be anticipated by the existence of tetracycline in any form in the prior art, even if it previously existed in mixture with another antibiotic substance. *Parke-Davis*, although noted for the general rule and exception referred to above, also recognized the principle that a broad claim which covers not only the pure form of a product, but the product in any environment, is anticipated by the prior existence of the product in mixture form (189 Fed. at 102).[23] Lidoff's citation of the case for this latter principle is evidenced by his statement that "the (apparent) mixture of the prior art meets the claims." It is further evidenced by the fact that in rejecting the Heinemann application on December 8, 1953, Lidoff cited *Parke-Davis* for that proposition alone.[24]

Apparently in support of the theory that pure tetracycline would have a different utility from Auremycin, the hearing examiner states: "In fact, the record establishes that tetracycline was an impurity in the prior art product

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[23] See S. H. Philbin's discussion of this aspect of *Parke-Davis* in *Judge Learned Hand and the Law of Patents and Copyrights*, 60 Harv. L. Rev. 394, 398 (1947).

[24] "Product claims 1 to 7, 18 to 20 are similarly rejected as being unpatentable over each of Duggar and Niedercorn since it appears, from the processes thereof, that applicant's product must be produced inherently. *The claims read on the product in any environment.* (See In re Kebrich, 671 O.G. 597 and Parke, Davis v. Mulford, 189 F. 95)" (CX 9, p. 31. Emphasis added.)

It should also be noted that *Parke-Davis* did not involve the question of "imparting utility". The facts of that case were that the pre-existing impure ingredient did impart its utility to a mixture (dried glands). The court found a difference in kind (rather than degree) to exist between the old mixture and the extracted ingredient because the dried glands contained other substances (organic tissue matter) which gave them dangerously toxic qualities. Lidoff was fully aware that Aureomycin products were therapeutically useful and not dangerously toxic as were the dried glands in the *Parke-Davis* case.

and rather than contributing to its utility detracted from it." This is not supported by the record and is contrary to what the evidence shows. But an impurity does not necessarily detract from utility. Both substances serve the same antibiotic purpose. To remove one is simply to obtain a purer but no more effective form of the other. Moreover, nothing indicated that tetracycline would limit Auremycin's utility.

Process v. Product Claim Rejections.

In support of his conclusion that Lidoff was interested only in knowing whether substantial quantities of tetracycline were coproduced, the hearing examiner theorizes that Lidoff applied different standards for product and process claims—that any amount of prior production would anticipate a process claim, but that only the production of "substantial" amounts would anticipate a product claim.[25] There is no indication that Lidoff so regarded the law. It appears that the source of this distinction lies in the fact that the hearing examiner, in imputing the "public use and sale" theory to Lidoff, could not otherwise account for process claim rejections.

In support of his theory that Lidoff required a greater quantum of inherent production of tetracycline to anticipate a product claim than to anticipate a process claim, the hearing examiner cites instances where Lidoff rejected process claims but not product claims on that basis. It is true that on October 29, 1953, Lidoff rejected the *product claims* in Heyden's Minieri application on the ground of anticipation by the Stephens' article and the *process claims on the ground of prior inherent production.*[26] Lidoff at this time sent notices to copy claims to Pfizer and Cyanamid

[25] Initial Decision, pp. 19-20, 29, 44-45.

[26] See p. 10 *supra* in this opinion.

indicating that an interference on the product tetracycline would be declared. He informed Minieri's attorney at the same time that if Minieri submitted an affidavit under Rule 131 swearing back of the Stephens' article that Minieri would then be eligible as a party to an interference on "tetracycline." Lidoff would not have rejected Minieri's product claims at the same time on the basis of inherent production since that would have barred Minieri from the proposed interference. (Lidoff had reason to have the question of priority among the three parties determined, as his theory of prior inherent production in the Duggar and Niedercorn processes was merely speculative and might later prove to be incorrect.) As it happened, Minieri did not enter the interference on the count for tetracycline as Cyanamid bought Minieri's rights from Heyden and elected to rely on the Boothe-Morton application in the first interference. *In the next ex parte office action in rejecting the Minieri claims, Lidoff was able to, and in fact did, reject Minieri product claims on the ground of prior inherent production.*

Lidoff first asserted the doctrine of inherent production against a product claim on December 8, 1953, in Bristol's Heinemann application. Lidoff at this time did not anticipate that Heinemann would be a party to any interference involving tetracycline as Heinemann was barred by the fact that the Stephens' article was published more than a year before the date of Heinemann's application. Therefore, there was nothing to prevent Lidoff from rejecting both process and product claims of Heinemann on the ground of prior inherent production and the product claim also on the basis of the Stephens article.[27]

As to the Martin-Bohonos (Cyanamid) rejection of process claims on the ground of inherent production on December 11, 1953, it is clear that Lidoff would not reject

[27] See p. 11 *supra* in this opinion.

the product claim therein on the basis of prior inherent production, since that would have been inconsistent with his previous notice to the common assignee Cyanamid to copy claims in the Boothe-Morton application on a proposed interference count on the product "tetracycline". As noted above, Lidoff, at this time, was favorable to having the question of priority settled in the first interference since his theory of inherent production in Duggar and Niedercorn was merely speculative and might later prove to be wrong. He could reject the Martin-Bohonos product claim on other grounds, however, which were not applicable to Cyanamid's Boothe-Morton application. This he did, citing the Stephens' article which was a statutory bar to the product claim in Martin-Bohonos, but not to the claim in the Boothe-Morton application which was to be included in an interference.

The hearing examiner, by his theory that there is difference in the law as to prior inherent production between product and process claims, is enabled thereby to dismiss two cases cited by Lidoff as involving process, not product claims. It must be noted at this point that the hundreds of pages of the file wrappers of various patent applications in the record reveal that Lidoff was thoroughly familiar with the patent law and it should not be easily inferred that he would cite a process case as precedent in rejecting a product claim unless the principle therein was equally applicable to both product and process claims. Furthermore, the hearing examiner, in characterizing the holding of *Allen* v *.Coe*,[28] misses the relevance of Lidoff's citation of that case, stating that it holds that what was claimed was obvious in the light of the disclosures of the prior patents. The hearing examiner concludes as to those cases:

> Both of those cases hold that what was claimed was obvious in the light of the disclosures in the prior

[28] *Allen* v. *Coe*, 135 F. 2d 11 (D.C.Cir., 1943); *In re Lieser*, 162 F. 2d 224 (C.C.P.A. 1947).

patents. No such theory is applicable to an undisclosed product present in a prior art mixture but unknown to anyone. Neither of these precedents were as much in point as *Cavallito*,[29] which involved an old known product with a newly discovered unknown component of the same utility.

Case Citations by the Patent Examiner.

Contrary to the above conclusion of the hearing examiner, these two cases (*Allen* v. *Coe* and *In re Lieser*) strongly support complaint counsel's interpretation of Lidoff's ruling, *i.e., that a prior disclosure of a process which inherently produces a product is equivalent in patent law to a disclosure of the product itself and that the later identification of the product does not constitute an invention. Allen* v. *Coe* involved an application for a patent for a process of using spent distillers' grain mash in the production of yeast of a high vitamin content which could be used as a therapeutic product. A prior patent to one Bacon described the process of using rice polish and spent distillers' grain mash in manufacturing yeast. Bacon had described the use of rice polish to the extent of about seven percent of the total preparation, but gave no proportion for the spent distillers' mash. The claimants, Allen and others, found that by using spent distillers' mash in the proper proportions they could obtain a yeast of high yield with high vitamin content. The court held that the Bacon patent anticipated their claim by disclosing a process which inherently produced vitamins in the end product even though this was unappreciated in the prior art. The court said:

> We agree with the lower court and with the Board of Appeals and the examiner that no invention is shown

[29] [*Ex parte Cavallito*, 89 U.S. P.Q. 449 (Pat. Off. B'd App. 1950)].

> over Bacon. It may well be that Bacon did not appreciate the importance of vitamins in the final product; but he unquestionably pointed out the high vitamin content of spent distillers' mash and taught its use in the molasses mineral salts process of yeast manufacture. The fact that he used the spent mash for increasing the yield of yeast rather than for increasing its vitamin content is immaterial, since a patent may not be granted for scientific explanations or discoveries of new uses or for unsuspected merit in old substances or processes. [Citing cases.]

The record is clear that Lidoff regarded the opinion as saying that the Bacon patent did not recognize the presence of vitamins in the final product so that it would disclose the yeast as a therapeutically useful product. We know this from Lidoff's citation of this case in connection with another legal issue that arose. In the dissolution of the second interference, in rejecting proposed fermentation counts on the basis of inherent production in the Duggar process, Lidoff stated:

> Duggar may not have *recognized* the presence of tetracycline in the fermentation broth, but he did recognize the antibiotic activity of the broth . . . There is no invention over Duggar in the *recognition* of additional advantages in his fermentation process, under the doctrine expressed in *Allen* v. *Coe,* 135 F. 2d 11 . . . (Emphasis added.)

The other case cited by Lidoff that was so lightly dismissed by the hearing examiner is *In re Lieser,* 162 F. 2d 224 (C.C.P.A. 1947). This case, as *Allen* v. *Coe,* supports our finding that Lidoff was relying on the theory that a prior patent could anticipate a later claim even though it did not "recognize" the significance of the inherent results of the process it discloses. In this case there was an appli-

cation for a patent on cuprammonium cellulose spinning solutions produced by dissolving cellulose in ammoniacal copper compounds. A prior reference, a patent to Gulbrandsen and others, had covered the same process but had specified the temperature for the solution to be 0° to 20° C. The Gulbrandsen patent added in the disclosures therein: "Temperatures considerably lower than 0° to 20° C are highly advantageous." Lieser's application specified –7° or –8° C. The issue was whether Gulbrandsen's patent anticipated Lieser's alleged invention. The court held that it did, stating that the language in Gulbrandsen, et al., "fairly suggests the use of temperatures as low as –7° or –8° C., and it is, therefore, immaterial whether the patentees anticipated that any particular desirable results would be obtained at those precise temperatures. *No invention is involved in following the teaching of the prior art, even if the results obtained are better than might have been expected.* [Citing cases.]" (Emphasis added.) The principle announced in this case was pertinent, notwithstanding the hearing examiner's conclusion to the contrary.

Lidoff, after citing the above two cases, then stated:

> It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the claims. (See Parke, Davis v. Mulford, 189 F. 95, and In re Kebrich, 96 U.S.P.Q. 411)

We have already explained our conclusion that *Parke-Davis* was cited by Lidoff for the general rule announced therein —that a purer form of an old product is not inventive— and that this case supports also the second principle stated in the above-quoted sentence—that a mixture in the prior art would meet Conover's broad claim for "tetracycline". The hearing examiner has erroneously used another holding in *Parke-Davis* to support his belief that Lidoff's theory was that tetracycline was patentable if it could be demonstrated that any tetracycline present in commercial Aureo-

mycin would not have imparted any degree of utility to the product. (Pages 88 and 89 of the Initial Decision)

The hearing examiner's handling of *In re Kebrich* also reveals how his preconceived notion of what the law *should be* as to the patentability of tetracycline has led him astray from the real issues: What was the ground of Lidoff's rejection of the Conover claim, and in overcoming that rejection, did Pfizer knowingly misrepresent or withhold material information? The hearing examiner characterizes *Kebrich* as follows:

> *Application of Kebrich* is a case where the court simply held that the claimed product had been disclosed in the prior art, a publication in the Chemical Journal. The Court held that the claimed product was substantially the same as that disclosed in the prior art. The Court distinguished and upheld *In re Williams,* considered next, . . .[30]

He then discusses *In re Williams,* 171 F. 2d 319 (C.C.P.A. 1948), and states that this case and still another not cited by Lidoff, "stand for the proposition we have here." He goes on to discuss *Williams* and shows how it supports the theory that tetracycline should be patentable. An analysis of *Kebrich,* however, reveals that it was accurately cited by Lidoff and that its holding is far more relevant to the instant case than the hearing examiner indicates. In *Kebrich* the court held that an application for the product dibasic lead stearate was anticipated by the description in a printed publication of dibasic lead stearate in mixture

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[30] The hearing examiner fails to appreciate the significance of how the court in *Kebrich* distinguished the *Williams* case. *Williams* was distinguished in *Kebrich* on the ground that the claim in that case was a narrow claim which excluded anticipation by a prior mixed compound. Kebrich, the court pointed out, was asserting a broad claim. Lidoff likewise was confronted by broad claims in Conover's application.

with monobasic lead stearate. The court held that as the applicant's claim was not limited to pure dibasic lead stearate it covered that product in any mixture and was thereby anticipated by the description in a printed publication. Thus, in the Conover application, "tetracycline" was broadly claimed and was not limited to any particular environment or degree of purity. Lidoff was saying in the last sentence of his rejection that the prior existence of tetracycline in the fermentation broth in mixture with Aureomycin would anticipate the broad claim for "tetracycline". Indeed, Pfizer's attorneys were well aware of this rule of law and understood Lidoff's statement. In the "Remarks" they filed on December 8, 1954, with the Tanner and Bogert affidavits they moved to amend their claims by adding narrower claims which covered tetracycline only in certain forms. Their reason was explained thusly:

> It was pointed out to him [Lidoff, during the previous interview] that there are substantial differences in scope between these two sets of claims, and that applicant should be granted claims 13 to 16 as insurance against some wholly unrecognized prior production of ineffective amounts of the products defined in claims 1 to 6. (CX 4, p. 39)[31]

This statement reveals another fact. It shows that Pfizer's attorneys understood that even small "ineffective" amounts of tetracycline in the Duggar and Niedercorn broths would be an anticipation of Conover's claim, and that Lidoff was not looking for only large quantities that would impart utility to the final commercial product.

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[31] Claims 2 to 6 were the original claims for tetracycline and its various salts. Claim 1 was a Markush claim using tetracycline and its salts as subgeneric species.

In spite of the context of the citation of these cases by Lidoff, the hearing examiner summarizes them in the following manner:

> The fact that Lidoff cited the *Parke, Davis, supra,* and *Kebrich* decisions demonstrated that he was aware of the possibility that, even if the presence of tetracycline in the prior art product had been known and disclosed, it might be patentable if it possessed utility different in kind rather than degree from the prior art product. This was the teaching of those decisions. (P. 89)

The cases cited by Lidoff, as we have shown, do not support the above characterizations. Rather, they support the finding that Lidoff was interested in the inherent production of tetracycline in the fermentation broth in mixture with Aureomycin under the processes disclosed in the Duggar and Niedercorn patents. The hearing examiner's characterization of the cases is but a summary of what the hearing examiner, on the basis of other decisions, has concluded the law should be.

ADDITIONAL ERRORS CONTAINED IN THE INITIAL DECISION.

In support of his theory of the law, the hearing examiner states:

> The actual fact of inherent production, namely, that Aureomycin contained from 2 to 5% tetracycline, demonstrated beyond doubt that the utility of Aureomycin was not due to the presence of tetracycline, and hence that tetracycline was patentable. (P. 91.)

This reasoning cannot be accepted by the Commission. This question of utility was never raised by Lidoff or anyone else.

Another misleading aspect of the hearing examiner's statement that Aureomycin contained from 2 to 5% tetra-

cycline is that Lidoff was never informed of this fact by Pfizer. After he had examined the Tanner and Bogert affidavits, which stated that no tetracycline could be recovered from the broths, Lidoff granted a notice of allowance to Pfizer. Under Patent Office procedure, a patent normally issues within a month of such notice. Six days before the issuance of the Pfizer patent on January 11, 1955, Lidoff's division received an affidavit from Bristol (the Taylor affidavit) in connection with Bristol's Heinemann application, which stated that 2 to 4% of tetracycline had been found in Aureomycin products, including products that had been placed on the market before the date of the Conover discovery of tetracycline. The hearing examiner, at page 88 of his decision, uses this as the basis for his conclusion that Lidoff *knew* that tetracycline was inherently produced and *therefore* he must have ruled that this was not enough tetracycline in old Aureomycin products to impart utility thereto, otherwise he would have taken action to halt the issuance of the patent.

This reasoning cannot be accepted for several reasons. As explained in our Findings[32] the Taylor affidavit did not refute Pfizer's tests. In addition, Lidoff could not make reference to such an affidavit in rejecting the Conover claim since it was filed in a confidential *ex parte* proceeding. Bristol, in filing the Taylor affidavit, did not waive its right to secrecy in regard to its Heinemann application. Therefore, Lidoff, even if his suspicions had been aroused by the Taylor affidavit, could not have shown the basis thereof, since the only evidence in the Conover file wrapper was an

[32] The Taylor affidavit did not constitute proof of inherent production of tetracycline in the Duggar and Niedercorn processes as disclosed in the prior art since the fact that tetracycline was contained in some commercial Aureomycin samples did not mean that its production was inherent or intrinsic in the processes in question using the NRRL-2209 microorganism which was the only one disclosed in the prior art. Respondents readily concede this latter point. See paragraph 26 of our Findings.

affidavit by an apparently equally reputable scientist as Dr. Taylor which stated categorically that no tetracycline was recovered from the broth fermented with NRRL-2209.

In connection with the hearing examiner's reasoning that Lidoff *knew* that tetracycline was inherently produced to some extent, it should be pointed out that Lidoff, after the Tanner and Bogert affidavits were submitted to him (which the hearing examiner erroneously states conceded to the Patent Office that 10% tetracycline was present in Aureomycin) and after the Taylor affidavit had been received, withdrew his original rejection in another Pfizer process application[33] and Pfizer received the patent on that process. The rejection in this application had been on the same ground on which Conover had been rejected—inherent production in the Duggar and Niedercorn processes. The hearing examiner neglects to explain how Lidoff "knew" that tetracycline was coproduced in the Duggar and Niedercorn processes in amounts up to 4%, 5% and 10% and at the same time allowed this process application.[34] The answer, of course, is that Lidoff did not know of coproduction in the prior art using the deposited microorganism NRRL-2209 and did not consider the Taylor affidavit as overcoming the Tanner and Bogert tests.

The hearing examiner's decision itself is inconsistent on the question of whether it was known to the Patent Office that tetracycline was coproduced if one followed the Duggar and Niedercorn processes. The initial decision at page 16 states that by the fall of 1953 it was general knowledge in scientific circles and the Patent Office that tetracycline was produced in Duggar and Niedercorn broths. This statement was made to support the finding that the

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[33] The Bogert and Walsh application for a process of separating tetracycline from Aureomycin.

[34] As stated before at p. 36 *supra,* the hearing examiner reasons that Lidoff's rationale was that the coproduction of *any amount* of tetracycline would bar a process claim.

Patent Office was interested only in whether the commercial product Aureomycin contained tetracycline as distinguished from the broth.[35] Yet at page 27 of his decision the hearing examiner finds that in response to a question by Lidoff, counsel for Cyanamid (Edelblute) filed in December 1953 a denial of any production of tetracycline by Cyanamid in its Aureomycin processes.[36] Also, he finds that on December 8, 1954, Pfizer filed an amendment and affidavits with the following statement:

> It was pointed out [at the last interview] to the Assistant Examiner that there is no reasonable basis for his speculation as to the coproduction of tetracycline in the prior art processes . . . [T]here are no statements whatever in the Minieri et al application to the effect that most strains of *Streptomyces aureofaciens* are capable of producing tetracycline under previously known fermentation conditions . . . Minieri et al themselves, in their brief on their motion to add fermentation counts in the interference . . . have stated that tetracycline could previously be produced only by deschlorination, and that there is no evidence of inherent production by the prior art processes. Most striking of all is the fact that the assignee of the Duggar and Niedercorn et al patents, who manufactured literally tons of chlortetracycline (Aureomycin) according to the methods described therein, failed to discover any tetracycline in such large-scale manufac-

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[35] The hearing examiner states that the fact that tetracycline was present in the resultant product, Aureomycin was not known at this time and did not become known until the Taylor affidavit was filed in the Heinemann application. The purpose of the Taylor affidavit, however, was to show that tetracycline was coproduced in the *broth,* as was so stated in the explanatory letter filed by Bristol. This shows that it was understood by Bristol that data as to coproduction in the broth was material information.

[36] See Paragraph 13 of the Findings, *supra.*

ture, although it devoted extensive research to the recovery, purification and properties of its patented antibiotic.

Pfizer then argued the law:

> It was further submitted to the Examiner that there is no proper basis in law for his rejection, even assuming that his speculation as to inherent co-production were correct. There are numerous court decisions establishing the rule 'novelty is not negatived by any prior accidental occurrence or production, the character and function of which was not recognized until later than the date of the patented invention sought to be anticipated thereby'. . . . It follows that a wholly unrecognized occurrence of some ineffective amount of tetracycline in a prior art product could not anticipate applicant's claims. (CX 34, pp. 34-6)

The Commission, on the basis of the record, cannot accept the hearing examiner's finding that by the fall of 1953 it was known by all, including Lidoff, that coproduction occurred in the Duggar and Niedercorn processes. The hearing examiner fails to understand that the fermentation applications submitted to Lidoff concerned processes which allegedly produced tetracycline for the *first time* by fermentation because they differed from the Duggar and Niedercorn processes in that they used an environment substantially free of chloride ions and used newly discovered microorganisms.[37]

The hearing examiner, in support of his conclusions, also uses the following reasoning: At page 89 of his deci-

[37] Bristol argues that its other applications (*Lien, et al., Gourevitch, et al., Chertow,* and *Hatch, et al.*) all disclosed the fact of coproduction. These, however, describe processes which utilized particular chloride-ion free conditions. See pp. 9 and 14 supra as to the significance of a chloride-free environment.

sion he surmises that Lidoff must have wanted to know whether tetracycline could be *recovered* from the broth by recovery techniques, as distinguished from mere identification by analytical research techniques, so that he could then assume that tetracycline was present in such "substantial" quantities that it must have been recovered along with Aureomycin and was present in the end product in (again) "substantial" quantities so that it imparted utility thereto. The hearing examiner states that 10% of tetracycline in the end product would not have been "substantial". He then states: "This fact, and the later proof of from 2 to 5%, demonstrated that the prior product did not contain substantial quantities of tetracycline and, hence, the utility of the prior product was not due to the presence of tetracycline. In fact, the record establishes that tetracycline was an impurity in the prior art product and rather than contributing to its utility detracted from it." At another place he states: "The presence of only 2 to 5% tetracycline in Aureomycin would have established to him that it was not recoverable as a separate therapeutic product." The above statements are examples of how the *a priori* reasoning of the hearing examiner has forced him to overlook uncontroverted evidence and to distort the evidence he does rely on. The arguments from the initial decision quoted immediately above are fallacious for the following reasons: Contrary to the argument of the hearing examiner, the Taylor affidavit *did* show that tetracycline was *recovered* from Aureomycin (the commercial product) by the Craig countercurrent separation procedure. (CX 9, p. 179, Tr. 9263) This is ignored throughout the entire initial decision. Secondly, the record nowhere shows that tetracycline ever detracted from the utility of commercial Aureomycin. Thirdly, the record nowhere indicates that five percent (or any other particular percentage) tetracycline in the final commercial product would not impart some antibiotic utility to the whole product

and to the contrary the record shows that even a small percentage of tetracycline in the final product would impart to it some antibiotic utility. (Tr. 4575)

The hearing examiner's explanation of why Lidoff wanted recovery tests used, as distinguished from non-recovery analytical tests, is not supported by the record. The "Remarks" filed by Pfizer's attorneys simply state: "The Examiner made it clear that he would not insist on a categorical averment that the fermentation broths prepared according to the cited patents contain no tetracycline whatsoever. He evidently appreciates the impossibility of proving its non-existence and is not concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic." (CX 4, p. 37) It is not necessary to speculate as to Lidoff's reason in having only recovery procedures used in the affidavit tests, since the record is clear that, whatever his reason may have been, Pfizer made false statements and withheld material information regarding the coproduction of tetracycline in recoverable quantities. Nevertheless, we think it is clear from the above explanation of the examiner's position that the purpose of the tests was to ascertain whether *any* tetracycline was coproduced and that the best and fairest means of determining this was to recover tetracycline in clearly identifiable form. The record indicates that positive identification of tetracycline is best established by recovery methods. (Tr. 9263-64)

Throughout his decision, the hearing examiner equates the following terms with one another—"recoverable quantities," "appreciable quantities," and "substantial quantities." The record nowhere indicates that Lidoff used the term "substantial quantities" as signifying what he considered to constitute coproduction. Lidoff never used the term "appreciable quantities" in his rejections. This term was used only in the "Remarks" and affidavits filed by

Pfizer in December 1954. Hutz, the author of the "Remarks," conceded on the witness stand that "appreciable quantities" was used synonymously with "recoverable quantities" and it is clear from the context in which the term was used that it was so intended. (Tr. 3627)

Constituting a necessary step in the hearing examiner's conclusion that no misrepresentation or withholding of information occurred is the hearing examiner's finding that Pfizer, in its Bogert affidavit, informed Lidoff that he could assume that the amorphous product Bogert recovered contained ten percent tetracycline. Examining the affidavit as a whole clearly reveals that Bogert merely stated that if this particular amorphous product contained no more than ten percent tetracycline there would be no way of recovering it, because ten percent of the .36 grams of amorphous material of a potency of 260 micrograms per milligram would mean that no more than .009 grams of tetracycline was present and such a minute amount could not be separated and recovered. This simply meant that as to this particular amorphous material, he could not recover tetracycline if it were there in a quantity constituting ten percent or less of the antibiotic material therein. The hearing examiner reasons that Pfizer, by conceding that its scientists could not detect ten percent tetracycline if it were present in that amorphous product, thereby conceded to the Patent Office that there *was* ten percent present and ten percent present in *all Aureomycin*. (Pp. 66, 69 of Initial Decision)

The hearing examiner has made a serious error in reasoning that if ten percent of the amorphous product recovered by Bogert was tetracycline then this would establish that ten percent of the antibiotics produced in the broth was tetracycline and that ten percent of the commercial product Aureomycin was tetracycline. The hearing examiner fails to take into account the fact that the amorphous

product resulted from a recovery procedure that was *selective* as to tetracycline, *i.e.*, the recovery procedure tended to isolate only tetracycline and leave substantial portions of other antibiotics such as chlortetracycline (Aureomycin) in the broth or in the filtrate. Assuming, for the purpose of illustration, that ten percent of the potency of the amorphous product was due to tetracycline and that the recovery technique left 95 percent of the total Aureomycin produced back in the broth or in the filtrate, then a simple calculation will show that the amount of tetracycline produced in the broth would be about one-half of one percent of the total antibiotic material. (Tr. 4456-60)[38]

Because of this error, the hearing examiner erroneously finds that the fact that 2 to 5% coproduction of tetracycline occurred would not have been of interest to Lidoff:

> The presence of only 2 to 5% tetracycline in Aureomycin would have established to him that it was not recoverable as a separate therapeutic product. This is further demonstrated by the fact that Pfizer requested the patent examiner to assume that as much as 10%, twice what the record reveals was present at most in old Aureomycin, was present in the amorphous product recovered from the test. In spite of this admission on the part of the applicant, the patent examiner promptly allowed the application. This demonstrates that knowledge of the presence of 2 to 5% tetracycline in old Aureomycin would have led him to the same conclusion. (I.D. at p. 62)

The hearing examiner concludes:

> No matter what fermentations were prepared or recovery methods applied, they could only have estab-

[38] Lidoff had no way of knowing the degree of selectivity. Since he was told that Procedure A was a "very efficient method for selective recovery" of tetracycline, he might well assume that the efficiency would be as high as stated above.

lished at the most that the resultant product contained less than 10% tetracycline, the amount Pfizer requested the patent examiner to assume. Pfizer did not withhold or misrepresent any information concerning inherent production. (I.D. at p. 66)

VIII

False Statements and Withholding of Information By Pfizer

The Commission, contrary to the above conclusion of the hearing examiner, finds that Pfizer made false statements to the Patent Office and withheld material information. The record shows that Lidoff was not interested in ascertaining any particular percentage figure of coproduction but wanted to know whether tetracycline could be recovered in clearly identifiable form from any of the media described in the Duggar and Niedercorn patents using the deposited microorganism NRRL-2209. The record indicates that Lidoff believed that Example 28, because of its low chloride ion content, was the most favorable of the media in Niedercorn for the production of tetracycline. Pfizer had discovered from previous tests that little potency was obtained using NRRL-2209 in the Example 28 medium. Dr. Bogert, in October 1954, determined that higher potencies were obtained using Example 1 of Niedercorn and that tetracycline was coproduced with Aureomycin.[39] Neither Bogert nor his superiors revealed this fact to the Patent Office. Bogert indicated in his monthly report to his superiors that tetracycline was known to exist in this type of broth and the evidence is undisputed that Bogert's tests were initiated at the request of Pfizer's pat-

[39] Subsequent tests run by Bristol using NRRL-2209 in the medium described in Example 1 of Niedercorn substantiate Bogert's previous findings that these potencies were much higher than those obtained in Pfizer's broths and that appreciable amounts of tetra-

ent officials. Although these officials deny they had knowledge of the results of Bogert's tests, they were under a duty to make inquiry before making the statement to the Patent Office that "The available evidence is overwhelmingly contrary to the Examiner's assumption."

The evidence of record also shows that Pfizer's representatives before the Patent Office withheld the fact that the test broths were unusually low in potency. The hearing examiner is in error in finding at page 65 that the weights and potencies of the recovered materials set forth in Bogert's affidavit made apparent the fact that the broths were low in potency. Since the recovery procedures employed by Bogert were to be selective as to tetracycline, Bogert's failure to recover anything but small amounts of amorphous material suggested to one not informed of the low antibiotic content of the broth that there was no significant production of tetracycline as compared to Aureomycin. The record clearly establishes that the potencies could not be calculated or reasonably estimated from information given to Lidoff. (Tr. 1912, 2869) In light of Hutz's testimony that great precautions were taken in conducting the tests and drafting the affidavits to make them invulnerable from attack in the forthcoming suit against Bristol, Squibb and Upjohn, it taxes credulity to believe

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cycline were produced. For instance, the following exhibits show the potencies and the percentages of tetracycline estimated from paper chromatography:

RPEx.	674-A	131 mcg/ml	5-10%
"	"	163 mcg/ml	5-10%
"	674-E	75 mcg/ml	20%
"	674-F	245 mcg/ml	20%
"	675-A	220 mcg/ml	5-15%
"	678-E	216 mcg/ml	5-15%

Tanner obtained a potency of 75 mcg/1 ml. in his October experiment. The higher potencies obtained by Bristol may be due to the fact that the fermentations were run for longer periods of time.

that the omission of this important fact from the papers filed with the Patent Office was inadvertent. It is of interest to note that in the depositions taken during the infringement suit, Bogert testified that he thought that the broth potencies had been included in Tanner's affidavit and for that reason did not mention them in his. (CX 37, p. 114)

Hutz and Murphy, Pfizer's patent representatives, claim that when they submitted the affidavits to Lidoff on December 8, they told him that NRRL-2209 was a poor producer and that the test broths had low potencies. They do not claim, however, that the actual potency figures were disclosed to Lidoff. Although Hutz or Murphy may have mentioned to him that NRRL-2209 was a relatively poor producer and was not the microorganism used by Cyanamid in its commercial production as they claimed they said, such a statement would not have been inconsistent with the representation that the test broth potencies were in the range of the potencies described in the Niedercorn patent. The Niedercorn potencies ranged from 109 to 396 micrograms of Aureomycin per milliliter, and commercial fermentation broths usually exceed 1,000 micrograms per milliliter. A casual remark to the effect that NRRL-2209 was a relatively poor producer and was not a commercially used microorganism would indicate only that it produced broths within the range of Niedercorn potencies or in the lower portion of this range It certainly would not constitute disclosure of the fact that the potencies were between 5 and 7 micrograms per milliliter, a mere fraction of the Niedercorn broth potencies. Dr. Tanner (the Pfizer scientist who prepared the test broths), for instance, described similar broth potencies that he had obtained in September 1954 experiments as being "miserable". (CX 33, p. 180)

The record also shows that information concerning the pH of one of the test broths was withheld. In response to

complaint counsel's proof that the pH of the Niedercorn broth during the first part of the tank fermentation exceeded the limits prescribed by Niedercorn and that this was not disclosed, the hearing examiner states that Tanner's affidavit specifically points out that the fermentation was adjusted to a pH of 6.7 because it was found to be higher than that recommended by Niedercorn. This is true, but what complaint counsel were attempting to show was that after the pH was thus adjusted, the medium was autoclaved (sterilized under pressure) and then *again* tested for pH. The test showed that the pH had risen to 8.1 and the medium was then inoculated and allowed to ferment for six and one-half hours even though this was at the limit of the range specified by Niedercorn and far outside the range recommended for optimum results. Contrary to what the hearing examiner indicates, the pH values during fermentation were not disclosed.

During the trial of this case, it was discovered by Cyanamid's research personnel that a typographical error was made in the Niedercorn patent and that ten times as much ammonium hydroxide was specified than was intended by Niedercorn and that this undoubtedly caused the high alkalinity. There is no proof that the high pH necessarily altered the end results of the experiment on broth 1771B. It may or may not have done so. Tanner did know, however, from his previous experiments with Niedercorn Example 28 that the pH could be expected to be too high and would have to be adjusted at some point. Furthermore, he related this fact to Dr. Murphy, who, together with Hutz, drafted Tanner's affidavit. (CX 34, pp. 57-58) Tanner, when questioned about this matter during the Bristol-Pfizer discovery proceedings, testified as follows:

Q. Did you have any discussion with anybody as to whether these pH's would be stated in the affidavit?

A. No. I presumed they would be. (CX 33, p. 239)

Pfizer's apparent purpose in withholding the above information was to put the affidavit tests in the best possible light so as to avoid the possibility that further tests would have to be made. Withholding of this information gave further credence to the impression the affidavits and accompanying papers conveyed to the patent examiner; namely, that the test broth potencies were within the general range of potencies described in the Niedercorn patent, and that no further tests need be conducted using Duggar and Niedercorn media.

The record also establishes that other procedures were available to Pfizer's scientists for recovering tetracycline in clearly identifiable form and that this fact was not disclosed to the patent examiner. Pfizer argues that the examiner would not have required these procedures as they were not commercial-type procedures. There is no indication in the summaries of oral interviews that he limited the recovery techniques to commercially feasible procedures. Although he did not require Pfizer to engage in "an elaborate research program" it was understood by Pfizer's representatives that this meant that Pfizer was not required to develop *new* recovery techniques. The very fact that Lidoff wanted an explanation of why Dr. Bogert did not make further attempts to isolate tetracycline from the minute amorphous products recovered from the test broths reveals that he did not specify that only commercial procedures be utilized.

THE TESTIMONY OF THE EXPERT WITNESSES.

Pfizer argues that the expert witnesses testifying for counsel supporting the complaint made a "complete about face" when brought back for rebuttal testimony after hearing respondents' scientists testify. Pfizer, for instance,

argues that Dr. Benedict[40] admitted on rebuttal that in following the Duggar and Niedercorn examples using the NRRL-2209 microorganism, he or any other skilled scientist would be more likely to produce broths having no potency than broths having the potencies obtained by Dr. Tanner. We cannot agree with this interpretation of Dr. Benedict's testimony. Dr. Benedict was examining various fermentations conducted by Bristol using Duggar and Niedercorn Example 28 media—not fermentations of *all* Niedercorn media. (Tr. 10,952-54, 10,970-72)

Bristol's records showed that 23 out of 26 tests using the NRRL-2209 in Duggar medium resulted in no potency and that three resulted in having potencies of 30, 37 and 37 mcg/ml. Bristol also performed eight tests using Niedercorn 28 and seven of these produced no potency and one produced a potency of 85 mcg/ml. As noted before, Bristol also conducted a number of tests employing Niedercorn Example I and obtained substantially greater potencies. The significance of the distinction between Duggar and Niedercorn Example 28 on the one hand and Niedercorn I on the other is pointed up by Dr. Benedict's answer to the following question posed by the hearing examiner:

> Based upon the tests that Bristol conducted that we have discussed at some length here, in your opinion as a scientist, would they have reason to believe, based upon that information which they had before them, that there was anything wrong with the tests conducted by Bogert and Tanner, and the information given the Patent Office?

* * *

[40] Dr. Robert Glen Benedict obtained his Ph.D. in Agricultural Bacteriology from the University of Wisconsin in 1936. In 1942 he joined the Northern Regional Laboratory of the United States Department of Agriculture where he was engaged in various types of research work involving antibiotics and fermentations. Dr. Benedict has authored about forty publications.

> [Dr. Benedict:] I think, your Honor, that what these experiments imply to me is the fact that Bristol was able to show by using Niedercorn No. 1 that appreciable quantities of tetracycline were co-produced with Aureomycin. I think that is quite emphatically pointed out here. They have also shown, of course, that in most cases they got nothing when they ran the Niedercorn and Duggar, rather than the [sic: rather the] Example 28 and the Duggar examples, and that to me is the significance of this. (Tr. 11,021)

Pfizer next argues that Dr. Benedict admitted on rebuttal that the pH of Tanner's broth did not depart from the instructions of Niedercorn Example 28. Another part of the Niedercorn patent, however, clearly gives the pH ranges for all the Niedercorn examples. Benedict was merely testifying that nothing was said in Example 28 to show whether the pH should be adjusted *before or after* sterilization. (Tr. 10,971) The significance of Tanner's pH was that it was allowed to remain at or slightly above the uppermost limit specified by Niedercorn and this fact was not disclosed. The Tanner affidavit implied that the pH was maintained in the optimum range (at 6.7, midway between 6.4 and 7.0) for the entire fermentation period.

Pfizer also argues that Dr. Stodola,[41] a witness for complaint counsel, agreed on rebuttal that the Craig counter-

[41] Dr. Frank H. Stodola received his Ph.D. in organic chemistry from the University of Minnesota. He worked under a fellowship at Yale University from 1934 to 1937, and at the Kaiser Wilhelm Institute for Biochemistry from 1937 to 1938, and at the Mayo Clinic and Columbia University in following years. In 1942 he joined the Northern Regional Laboratory of the United States Department of Agriculture where he was put in charge of the Chemistry Section of the Fermentation Division. Dr. Stodola's work is primarily in the isolation, characterization, and structure determination of new fermentation products, and he is an expert on the isolation and separation of antibiotics.

current procedure could not be applied to fermentation broths and that he knew of no chromatography procedure available prior to Conover's discovery which was suitable for recovering tetracycline from fermentation broths. Pfizer's argument has no relevance to the issues, however. No one contends that the Craig procedure is applied *directly* to fermentation broths. Rather, it is applied to solid products recovered from the broths. (Tr. 11,041-42) Furthermore, the evidence is undisputed that Lidoff did not require pre-Conover or "prior art" types of recovery procedures, but required the use of any procedures currently known to be suitable for recovering and isolating tetracycline.

Pfizer points out that Stodola also agreed that the ratio of tetracycline to Aureomycin is more important than the total antibiotic potency of the broth in determining whether tetracycline can be recovered. This, however, in no way detracts from the evidence that where tetracycline constitutes a fixed percentage, such as five to ten percent of the antibiotic material, it is easier to recover tetracycline from a higher potency broth than from a lower potency broth. (See, e.g., Tr. 11,031)[42]

Pfizer next argues that Dr. Stodola repudiated his former testimony by stating on rebuttal that the procedures used by Dr. Bogert were good ones for recovering tetracycline from the fermentation broths, and that they were the very procedures he would have selected. This is a distortion of Stodola's testimony. He merely testified that one or more of these methods could be used initially to concentrate the antibiotics in Tanner's broths into crude form. (Tr. 11,042) He clearly pointed out that due to the low potency of these broths the tetracycline would not be directly isolated but that further purification and isolation

[42] The hearing examiner at page 63 of his decision incorporates Dr. Stodola's statement as a finding without mentioning this fact. This finding, standing alone, gives an erroneous impression.

procedures would have to be used. (Tr. 1943-46; 11,052) There is no inconsistency in this and his earlier testimony to the effect that Bogert's procedures were not designed to directly isolate tetracycline from the broths of the potencies obtained by Tanner.

Pfizer representatives intentionally created several false impressions in the papers filed with the patent examiner. One of these was their statement that the available evidence was contrary to the examiner's speculation that tetracycline had been produced in Aureomycin fermentations. This conveyed the definite impression that any tests that Pfizer had performed gave negative results. In fact, the same Pfizer scientists who conducted the affidavit tests for the Patent Office had earlier obtained positive results that coproduction did occur in one of the prior art processes. Pfizer's representatives before the Patent Office deny that they had knowledge of these tests. They do not claim, however, that they made any effort to ask these Pfizer scientists if they had ever found evidence of coproduction.

Where fraud in the procurement of a patent has been alleged in infringement suits and cancellation proceedings, the courts have stated that it must be established by clear and convincing evidence that the false or misleading statement was made (or information was withheld) deliberately and with intent to deceive.[43] Also, of course, the information that is misrepresented or withheld must be material.[44]

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[43] *United States* v. *American Bell Telephone Co.*, 167 U.S. 224 1897; *Haloro, Inc.* v. *Owens-Corning Fibreglas Corporation*, 266 F. 2d 918 (D.C. Ct. App. 1959); *Huszar* v. *Cincinnati Chemical Wks.*, 172 F. 2d 6, 11 (6th Cir., 1949); *Martin* v. *Ford Alexander Corp.*, 160 F. Supp. 670 (S.D. Cal. 1958); *United States* v. *Standard Electric Time Co.*, 155 F. Supp. 949 (D. Mass. 1957); *Marks* v. *Polaroid Corporation*, 129 F. Supp. 243 (D. Mass. 1955), aff'd 237 F. 2d 428 (1st Cir., 1956).

[44] *Hazel-Atlas Co.* v. *Hartford-Empire Co.*, 322 U.S. 238 (1944). See *Admiral Corp.* v. *Zenith Radio Corp.*, 296 F. 2d 497 (10th Cir., 1961) where the court implied that a higher duty to disclose exists where the information is not accessible to the Patent Office.

In order for the government to prosecute successfully a suit for patent cancellation, common law fraud must be proven. From an examination of the record as a whole, Pfizer's conduct before the Patent Office in misrepresenting and withholding certain information would warrant a judgment for cancellation. *But we do not find such a holding necessary to our disposition of the case.* Rather, we conclude that such conduct at the very least amounted to "unclean hands", "inequitableness" and "bad faith".[45] Under

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[45] In *Precision Instrument Manufacturing Co., et al.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), 814, 819, Justice Murphy noted doctrines of equity which we think are applicable here:

> The guiding doctrine in this case is the equitable maxim that 'he who comes into equity must come with clean hands.' This maxim is far more than a mere banality. It is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant. That doctrine is rooted in the historical concept of court of equity as a vehicle for affirmatively enforcing the requirements of conscience and good faith. This presupposes a refusal on its part to be 'the abetter of iniquity'." Bein v. Heath 6 How. 228, 247, 12 L. Ed. 416. Thus while "equity does not demand that its suitors shall have led blameless lives," Loughran v. Kkughran, 292 U.S. 216, 229, 54 S. Ct. 684, 689, 78 L. Ed. 1219, as to other matters, it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue. Keystone Driller Co. v. General Excavator Co., 280 U.S. 240, 54 S. Ct. 146, 147, 78 L. Ed. 293; Johnson v. Yellow Cab Transit Co., 321 U.S. 383, 387, 64 S. Ct. 622, 624, 88 L. Ed. 814; 2 Pomeroy, Equity Jurisprudence (5th Ed.) §§ 397-399.

More specifically on the patent phase, the Court held that:

> . . . Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue. Cf. Crites, Inc. v. Prudential Ins. Co., 322 U.S. 408, 415, 64 S. Ct. 1075, 1079, 88 L. Ed. 1356. This duty is not excused by reasonable doubts as to the sufficiency of the proof of the inequitable conduct nor by resort to independent legal advice. Public in-

these circumstances, to allow Pfizer to raise its patent as a shield against the antitrust laws would be a blatant distortion of the purpose behind the patent laws. That the public should receive something new and useful from the holder of a patent is manifestly clear. And in this case Pfizer was clearly unwilling to reveal material information bearing on whether or not the public was in fact receiving the above benefits.

We hold that under the circumstances it was an act of deliberate misrepresentation of fact and suppression of information for the Pfizer patent officials to claim that the "available evidence is overwhelmingly contrary" to the examiner's assumption without having made any effort to ask Pfizer officials and scientists whether such assertion was correct. These Pfizer officials could not close their eyes to evidence which was close at hand which belied their statement.

Although it is impossible to determine for certain what would have occurred had Pfizer chosen to disclose all the information it had—the coproduction of tetracycline in Niedercorn Example I and the unusually low potency of the test broths—it can be reasonably inferred that Lidoff would have required a duplication of Niedercorn Example I and that Pfizer scientists could have recovered tetracycline from such a fermentation broth. But it is not really necessary to determine what would have occurred had Pfizer not made misleading statements and had disclosed the information, as long as the statements and the information with-

terest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies. Only in that way can the the 'mute and helpless victims of deception and fraud.' Hazel-Patent Office and the public escape from being classed among Atlas Glass Co. v. Hartford-Empire Co., supra, 322 U.S. 246, 64 S. Ct. 1001, 88 L. Ed. 1250.

held were material to the examiner's determination of the patentability of tetracycline. *Hazel-Atlas Co.* v. *Hartford-Empire Co.*, 322 U.S. 238 (1944).

IX

Alleged False Statements and Withholding of Information by Cyanamid and Bristol

In addition to the misleading statements and withholding of material information made by Pfizer, the record shows that various statements denying concomitant production were made by Edelblute, Cyanamid's patent attorney, to examiner Lidoff both before and during the second interference in connection with Cyanamid's Boothe-Morton and Minieri applications. These statements made Pfizer's failure to recover tetracycline seem all the more plausible. The record shows that Cyanamid, as early as December 1953, had evidence that tetracycline was present in its Aureomycin products and that this information was not disclosed to the patent examiner. (CX 81)[46]

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[46] Commission exhibit 81 is a Cyanamid interoffice memorandum which states in part: "A further search of our records indicates that we submitted a considerable number of production samples, dating back to early 1949, to Mr. Martin during December, 1953, with a request for chromatographic analysis for tetracycline. Verbal reports from him during the latter part of December, 1953, qualitatively established the presence of tetracycline in both current and early Aureomycin. This would appear to have been our first definite knowledge of the contamination of product crystals by tetracycline."

In February of 1954, copies of a memorandum containing the information that four samples of Aureomycin contained one to six percent tetracycline were distributed to various officials. It states on the memorandum that a copy was sent to Edelblute. (CX 111B) Edelblute, therefore, knew of or had ready access to information which contradicted his previous assurances to the examiner that tetracycline was not produced in the manufacture of Aureomycin. Edelblute denies that he received a copy of this memorandum. This would not excuse Cyanamid, however, from failing to correct the false statements. Furthermore, by his own admission, he knew of the fact of coproduction by December 1954. At this time, Cyanamid's

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Similar tests on commercial Aureomycin made by the other respondents substantiate Cyanamid's findings. Pfizer had subjected a capsule of Aureomycin to a Craig countercurrent in the fall of 1954 and determined by that method and by paper chromatography that tetracycline constituted 2 to 4 percent of the many samples tested. Squibb's laboratories analyzed commercial Aureomycin and concluded that it contained about 5 to 10 percent tetracycline. Upjohn analyzed a sample of Cyanamid's Aureomycin and found it to contain 3.5 to 4 percent tetracycline. The tetracycline content was confirmed by Craig countercurrent analysis.

As a result of Cyanamid's withholding of the truth, Pfizer was aided in its endeavor to convince the patent examiner that tetracycline was a new product and did not exist in the prior art. Although disclosure by Cyanamid of the presence of tetracycline in commercial Aureomycin would not conclusively have proven the existence of recoverable amounts of tetracycline in NRRL-2209 fermentations,[47] it is obvious that the categorical denial by Cyanamid of the coproduction of tetracycline strengthened Pfizer's position.

Cyanamid argues that it was under no duty to correct the statements made by its patent attorney because it appeared that the examiner withdrew from his position (regarding the relevance of inherent production) by reason of the declaration of the second interference in February of 1954. This does not afford Cyanamid an excuse to allow false statements to remain on record. Edelblute's statement (in response to an inquiry by examiner Lidoff) that

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and Pfizer's applications were still pending before the patent examiner and he had opportunity at that time, at least, to correct the record. He failed to do so, however, until many months after the Pfizer patent was issued.

[47] Cyanamid representatives testified that the NRRL-2209 microorganism deposited by Cyanamid was not used in commercial operations.

Cyanamid's tests revealed that no tetracycline was concomitantly produced might well have been a factor in the examiner's withdrawal from that position.[48] Moreover, Rule 237 of the Patent Office Rules of Practice makes it clear that the determination of patentability in declaring an interference is not conclusive and may be reversed by the examiner. Edelblute was obviously aware of this possibility since he reassured the examiner on two occasions during the second interference that inherent production did not occur. (CX 12, pp. 36, 381-83)[49]

Cyanamid's acceptance of a license in January of 1955 under the newly issued Conover patent with the knowledge that it made false statements of fact to the Patent Office and that these statements bore directly on the question of patentability of tetracycline, constituted an illegal attempt on its part to share in a monopoly on tetracycline. If, before the dissolution of the second interference, Cyanamid had corrected the record and had disclosed the information it had concerning inherent production, Pfizer undoubtedly would have been deterred from attempting to convince the examiner that tetracycline could not be recovered from the prior art broths. Moreover, Pfizer would not have been able to state to Lidoff that: "The available evidence is overwhelmingly contrary to the Examiner's assumption . . . Most striking of all is the fact that the assignee [Cyanamid] of the Duggar and Niedercorn, et al. patents, who manufactured literally tons of chlortetracycline (Aureomycin)

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[48] Cyanamid's argument that Edelblute's statement could not have influenced Lidoff since Lidoff "later" rejected Bristol's Heinemann claims on inherent production is without substance. The record shows that Lidoff's division of the Patent Office did not even receive Edelblute's statement until the day before Heinemann's rejection was mailed out. (CX 5, p. 44)

[49] By this time Cyanamid had performed numerous tests, all of which consistently showed that tetracycline, contrary to Edelblute's statement, was inherently produced. (CX 81, 79A, 80, 110 B, 111 A & B, 114)

according to the methods described therein, failed to discover any tetracycline in such large scale manufacture . . ."

Complaint counsel also charge Bristol with making false statements of fact to the Patent Office and withholding material information. We cannot agree that the evidence sustains the charge that Bristol made false statements or was under a clear duty to disclose the information it had concerning inherent production. Bristol's attorneys never denied coproduction but simply argued that the Duggar and Niedercorn patents did not disclose this fact.

X.

Applicability of Section 5 of The Federal Trade Commission Act

A.

At various times in this proceeding, Pfizer, Cyanamid, and Bristol have taken the position that this Commission lacks jurisdiction to make inquiry as to the methods used to obtain the Conover patent. This contention, as it is set forth in Pfizer's brief, is based primarily upon 28 U.S.C. Sec. 1338(a), which provides that:

> The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent and copyright cases.

Pfizer's argument, as we understand it, is twofold: (1) Since Congress has expressly given Federal courts original jurisdiction exclusive of state courts over civil actions arising under any Act of Congress relating to patents, Congress has by implication given Federal courts exclusive jurisdiction vis-a-vis all other tribunals, including the Federal Trade Commission; and, alternatively, (2) since Congress,

in enacting the Federal Trade Commission Act, did not expressly confer jurisdiction over patent matters, this Commission lacks authority under the law to question the validity of a United States patent. Pfizer attempts to bolster the first of these two arguments by quoting dictum in *United States* v. *American Bell Telephone*, 128 U.S. 315 (1888), to the effect that the Federal courts alone can annul or cancel a patent issued by the Commissioner of Patents.

Pfizer's arguments fail to take into account the judicial interpretation of 28 U.S.C. Section 1338(a) and other pertinent Supreme Court decisions. Moreover, the *American Bell Telephone* case involved an action in the nature of an *in rem* proceeding to cancel a patent obtained by fraud. This proceeding is of a different nature; it is grounded on the allegation in the complaint that respondents have committed unfair acts of competition in violation of the Federal Trade Commission Act. The distinction is one not without meaning. Cf. *Becher* v. *Contoure Laboratories, Inc.*, 279 U.S. 388 (1929) and *United States* v. *U.S. Gypsum Co.*, 333 U.S. 364 (1948), discussed below. That the legitimacy of the actions of Pfizer and Cyanamid before the Patent Office is drawn into question does not, in our opinion, deprive this Commission of jurisdiction to issue an appropriate cease and desist order.

Section 1338(a) of the Judiciary Code of 1948 merely adopted language used for the first time in U.S. Rev. Stat. 134, Sec. 711(s) (1878). Since the Federal Trade Commission, as well as other quasi-judicial agencies, were created in later years, no inference can be drawn from the statute that Congress made federal court jurisdiction of actions arising under patent laws exclusive of this Commission as well as state courts. Furthermore, the "exclusive" jurisdiction given to federal courts has by no means completely circumscribed the power of state courts to decide cases involving patents. State courts have jurisdiction to rule on the validity of patents when the issue is incidental or

collateral to the plaintiff's cause of action. *Pratt* v. *Paris Gas Light & Coke Co.*, 168 U.S. 255 (1897); *American Well Works Co.* v. *Lane & Bowler Co.*, 241 U.S. 257 (1916); *MacGregor* v. *Westinghouse Electric & Mfg. Co.*, 329 U.S. 402 (1947). In one case a state court entertained a bill asking for assignment of a patent to the plaintiff, based on the claim that the defendant took the invention from the plaintiff in breach of trust and illegally obtained the patent in his own name. Although such a fact, if established, would constitute fraud on the Patent Office, the Supreme Court upheld the state court's jurisdiction to make this finding. In so holding, the Court enunciated the following principle which we think is apropos to this proceeding:

> That decrees validating or invalidating patents belong to the Courts of the United States does not give sacrosanctity to facts that may be conclusive upon the question in issue. A fact is not prevented from being proved in any case in which it is material, by the suggestion that if it is true an important patent is void. *Becher* v. *Contoure Laboratories, Inc.*, 279 U.S. 388, 391 (1929).

We conclude from the above precedents that there is nothing within 28 U.S.C. Sec. 1338(a) which would prevent this Commission from investigating unfair methods of competition before the Patent Office.

B.

While it has been argued that the grant of a monopoly is an exception in an unrestrained free enterprise system,[50] it is an exception which has been anticipated by the Framers of the Constitution.

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[50] "With us free enterprise is the rule, the grant of patent for invention or discovery the exception." *Patents and Free Enterprise* TNEC Monograph No. 31, p. 158 (1941). See generally—Hamilton, *Common Right, Due Process and Antitrust*, 7 Law & Contemp. Prob. 24 (1940).

The Patent-Copyright Clause, Article I, Sec. 8, provides:

> "Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

The relevant federal statutes are contained in the Patent Code of 1952, 66 Sta. 792, 35 U.S.C. Sec. 1-293. With similar constitutional authority enabling it to regulate commerce, Congress has enacted the antitrust laws. In a landmark case, *United States* v. *Line Material Co., et al.*, 333 U.S. 287, 308, 309 (1948), the Supreme Court has articulated the relationships between these two laws:

> Thus we have a statutory monopoly by the patent law, and by the Sherman Act a prohibition not only of monopoly or attempt to monopolize but of every agreement in restraint of trade. Public policy has condemned monopolies for centuries [cases cited]. Our Constitution allows patents, Article I, Sec. 8, Cl. 8.
>
> The progress of our economy has often been said to owe much to the stimulus to invention given by the rewards allowed by patent legislation. The Sherman Act was enacted to prevent restraints of commerce but has been interpreted as recognizing that patent grants were an exception. *Bement* v. *National Harrow Co., supra,* 92 91 Cong. Rec. 2457. Public service organizations, governmental and private, aside, our economy is built largely upon competition in quality and prices. *Associated Press* v. *United States,* 326 U.S. 1, 12-14. Validation by Congress of agreements to exclude competition is unusual. Monopoly is a protean threat to fair prices. It is a tantalizing objective to any business compelled to meet the efforts of competitors to supply the market.

And the words of Judge Learned Hand precisely parse the philosophy behind the antimonopoly legislation:

> "Throughout the history of these statutes [the antitrust laws] it has been constantly assumed that one of their purposes was *to perpetuate and preserve for its own sake* and in spite of possible cost, an organization of *industry in small units which can effectively compete with each other.*" *U.S.* v. *Aluminum Co. of America,* 148 F. 2d 416, 429 (2nd Cir. 1945).

This agency also has its very roots planted in that philosophy so precisely phrased by Judge Hand. Indeed, there is a breadth and scope to the meaning of "unfair methods of competition" which may be unduplicated in the entire administrative process.[51] Obviously, it is difficult to define the limits or to articulate with precision the meaning of unfair methods of competition. But this was the very thrust of the congressional purpose. The framers of the Federal Trade Commission Act envisioned its breadth and purposefully left flexible the catalog of offenses to be encompassed under this broad statutory mandate.

The 1914 Committee Report containing the recommendation that "unfair methods of competition" be prohibited emphasizes this point:

> One of the most important provisions of the Bill [S. 4160] is that which declares unfair competition in commerce to be unlawful, and empowers the Commission to prevent corporations from using unfair methods of competition in commerce by orders issued after hearing, . . .

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[51] In the words of Professor Jaffe the Federal Trade Commission was "a landmark in legislation because it subjected business in general rather than a limited area such as transportation, gas, or electricity to administrative process"; Jaffe, *Cases on Administrative Law, Introduction* 10 (1954). See also Jaffe & Nathanson *Cases on Administrative Law,* Introduction 13 (1961).

> The Committee gave careful consideration to the question as to whether it would attempt to define the many and variable unfair practices which prevail in commerce and to forbid [them] . . . or whether it would, by a general declaration condemning unfair practices, leaving it to the Commission to determine what practices were unfair. It concluded that the latter course would be better, for the reason as stated by one of the representatives of the Illinois Manufacturer's Association, that there were too many unfair practices to define, and after writing 20 of them into law it would be quite possible to invent others.
>
> It is believed that the term "unfair competition" has a legal significance which can be enforced by the Commission and the courts, and that it is no more difficult to determine what is unfair competition than it is to determine what is a reasonable rate or what is an unjust discrimination. The committee was of the opinion that it would be better to put in a general provision condemning unfair competition than to attempt to define the numerous unfair practices such as local price cutting, interlocking directorates and holding companies intended to restrain substantial competition.[52]

Though every Sherman Act violation is encompassed within the scope of "unfair method of competition",[53] and

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[52] S. Rep. 597, 63d Cong. 2d Sess. (1914) at 13. Later the "Covington Bill" was referred to this same Committee which recommended that the "Newlands Bill" be substituted for it.

[53] With respect to jurisdiction, there is, of course, a difference in the "Commerce" requirements of the two statutes. The Supreme Court over 20 years ago held that the Sherman Act comprehended those restraints of trade which "affected interstate commerce". On the other hand, the Court stated that the Federal Trade Commission Act was limited to those unfair methods of competition which occurred "in commerce". See *Federal Trade Commission* v. *John Bunte & Bros., Inc.*, 312 U.S. 349 (1941). The validity of this distinction is not material to this decision.

since all unfair methods of competition are not necessarily Sherman Act violations, this Commission's *original* jurisdiction is clearly not restricted to these offenses which have been adjudicated to be violations of the Sherman Act. And the Supreme Court has persistently reiterated this theme and resisted all attempts to establish a comprehensive itemized list of unfair methods of competition. In *Federal Trade Commission* v. *Cement Institute, et al.*, 333 U.S. 683 (1948) Justice Black has met squarely the issue of the breadth of the Commission's jurisdiction:[54]

> . . . this court has pointed out many reasons which support the interpretation of the language "unfair methods of competition" in Section 5 of the Federal Trade Commission Act as including violations of the Sherman Act. Thus it appears that soon after its creation the Commission began to interpret the prohibitions of Section 5 as including those restraints of trade which also were outlawed by the Sherman Act, *and that this court has consistently approved that interpretation of this Act.* (Emphasis added) (333 U.S. at 691.)

* * * * *

[54] The context for this discussion was set out as follows by Justice Black:

> "Marquette contends that the facts alleged in Count I do not constitute an unfair method of competition within the meaning of Section 5. Its arguments run this way: Count I in reality charges a combination to restrain trade . . . Section 4 of the Sherman Act provides that the Attorney General shall institute suits under the Act on behalf of the United States and that the Federal district courts shall have exclusive jurisdiction of such suits. Hence, continue respondents, the Commission, whose jurisdiction is limited to "unfair methods of competition" is without power to institute proceedings or to issue an order with regard to the combination in restraint of trade charged in Count I." *Federal Trade Commission* v. *Cement Institute, et al., supra,* at 689-90.

We adhere to our former rulings. The Commission has jurisdiction to declare that conduct tending to restrain trade is an unfair method of competition even though the self same conduct may also violate the Sherman Act.

There is a related jurisdictional argument pressed by Marquette which may be disposed of at this time. . . . Marquette and 88 other cement companies . . . [have been charged with] violating Section 1 of the Sherman Act. . . Marquette urges that the Commission proceeding should now be dismissed because it is contrary to the public interest to force respondents to defend both a Commission proceeding and a Sherman Act suit based largely on the same alleged misconduct.

We find nothing to justify a holding that the filing of a Sherman Act suit by the Attorney General requires the termination of these Federal Trade Commission proceedings. In the first place, although all conduct violative of the Sherman Act may likewise come within the unfair trade practice prohibitions of the Trade Commission Act, the converse is not necessarily true. *It has long been recognized that there are many unfair methods of competition that do not assume the proportions of Sherman Act violations. Federal Trade Commission* v. *R. F. Keppel & Bros.*, 291 U.S. 304; *Federal Trade Commission* v. *Gratz*, 253 U.S. 421, 427. Hence a conclusion that respondents' conduct constituted an unfair method of competition does not necessarily mean that their same activities would also be found to violate Section 1 of the Sherman Act. In the second place the fact that the same conduct may constitute a violation of both Acts in nowise requires us to dismiss this Commission proceeding. . . . Both the legislative history of the Trade Commission Act and its specific language indicate a congressional purpose, not to confine each

> of these proceedings within narrow, mutually exclusive limits, but rather to permit the simultaneous use of both types of proceeding. Marquette's objections to the Commission's jurisdiction are overruled. (Emphasis added) (333 U.S. at 693-95.)

As we initially stated, the monopoly granted by the patent laws is a clear but narrow exception to our free enterprise system. The thought that monopoly power may be acquired through fraud,[55] unclean hands, inequitableness or bad faith,[56] or any borderline behavior before the Patent Office[57] has manifest connotations of unfairness. Ironic indeed would be the result if this Commission—with power against partial, incipient and various other hybrid monopolies—could not arrest the continuance of an absolute monopoly procured by unfair methods.

Again in *Fashion Originators Guild* v. *F.T.C.*, 312 U.S. 457, 466 (1941), the court pointed out:

> Petitioners, however, argue that the combination cannot be contrary to the policy of the Sherman and Clayton Acts since the Federal Trade Commission did not find that the combination fixed or regulated prices, parcelled out or limited production, or brought about a deterioration in quality. But action falling into these three categories does not exhaust the types of conduct banned by the Sherman and Clayton Acts. *And as previously pointed out, it was the object of the Federal Trade Commission Act to reach not merely in their fruition but also in their incipiency combinations which*

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[55] See *Hazel-Atlas Glass Co.* v. *Hartford-Empire Co.*, 322 U.S. 246 (1943).

[56] See *Precision Instruments Mfg. Co., et al.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

[57] See *U.S.* v. *The Singer Manufacturing Company*, 31 U.S. L. Week 4674 (U.S. June 17, 1963).

could lead to these and other trade restraints and practices deemed undesirable. (Emphasis added)

For 75 years, the right of the United States to obtain cancellation of a patent procured by fraud has been clearly established.

> That the government authorized both by the Constitution and the statutes to bring suits at law and in equity, should find it to be its duty to correct this evil, to recall these patents, to get a remedy for this fraud is so clear that it needs no argument. . . . (*United States* v. *American Bell Telephone,* 128 U.S. 315, 370 (1888).

While admittedly respondents' actions may constitute a violation subject to prosecution by more than one governmental party, contrary to respondents' urging, clearly our action is neither a pre-emption nor usurpation of the Attorney General's right to file suit for cancellation.

It is also evident to us that the bringing of the instant case represents no revolutionary theory. Over the past quarter century the Justice Department, in a series of landmark cases, has attacked the *abuse* of patent monopolies, alleging that the grant from the government had been utilized in such a way as to contravene the antitrust laws. See *United States* v. *Masonite Corp.,* 316 U.S. 265 (1942); and *United States* v. *Line Material Co., et al.,* 333 U.S. 287 (1948).

In *United States* v. *United States Gypsum Co., et al.,* 333 U.S. 364 (1948), the government had filed a complaint charging violations of Sherman 1 and 2. Approximately two years later, the Attorney General amended the complaint to charge "that the article claims of five patents owned by United States Gypsum were invalid and void." The defendants moved to strike the amendment on the ground that the government was estopped to attack the validity of the patents in the present proceedings, and that

such attack would constitute a review of action by the Commissioner of Patents which was not authorized by statute. The lower court granted defendant's motion. The Supreme Court, specifically stating that, upon its view of the Sherman Act charges, it did not have to decide this issue (whether the government had the standing to challenge the validity of the patent), went out of its way to overrule the lower court. The Court stated at pp. 387-388:

> "While this issue need not be decided to dispose of this case it seems inadvisable to leave the decision as a precedent. *Hurn* v. *Oursler,* 289 U.S. 238, 240. The United States does not claim that the patents are invalid because they have been employed in violation of the Sherman Act and that a decree should issue cancelling the patents; rather the government charges that the defendants have violated the Sherman Act because they granted licenses under patents which were in fact invalid. If the government were to succeed in showing that the patents were in fact invalid, such a finding would not in itself result in a judgment for the cancellation of the patents . . . "

[Correction per Commission Order of 1/3/64.]

> In an antitrust suit instituted by a licensee against his licensor, we have repeatedly held that the licensee may attack the validity of the patent under which he was licensed because of the public interest in free competition even though the licensee has agreed in his license not to do so [cases cited].
>
> In a suit to vindicate the public interest by enjoining violations of the Sherman Act the United States should have the same opportunity to show that the asserted shield of patentability does not exist. Of course this appeal must be considered on a record that assumes the validity of all the patents involved."

Recently the Supreme Court cited *U.S.* v. *U.S. Gypsum Co., et al.*, 333 U.S. 364 (1948), and had an opportunity to reiterate its concern with the standard of conduct before the Patent Office.[58]

In short, if the government may assert the *invalidity* of a patent in an antitrust suit, then this agency certainly can pass on the manner in which Pfizer procured its patent on tetracycline, ". . . and one need not resort to metaphysical subtleties to denominate its conduct an unfair method of competition." (*Grand Union Co.* v. *F.T.C.*, 300 F. 2d 92, 99 (2d Cir., 1962).)

We are not holding that every misrepresentation of fact or withholding of material information before the Patent Office necessarily constitutes *per se* an unfair method of competition under the Federal Trade Commission Act. Some patents may be commercially worthless or have no adverse effects on competition. The facts of this case, however, are that a patentee has asserted monopoly rights under a patent so acquired and, as a consequence thereof, has restrained competition in the manufacture and sale of an important antibiotic; in at least one year the annual sales of tetracycline exceeded $100,000,000. The record further

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[58] See *United States* v. *The Singer Manufacturing Company*, 31 U.S. L. Week 4674 (U.S., June 17, 1963).

Also of considerable interest on this point are the following comments:

> "A recent report [S. Rep. No. 97, 82d Cong., 1st Sess. (1961)] by the Senate Subcommittee on Patents, Trademarks, and Copyrights noted that in sixty applications examined by it in which a final rejection was overcome by affidavits a 'substantial number' of the affidavits did not appear sufficient for that purpose. It thus appeared to the Subcommittee that the half-truths which had misled the examiners in those cases presented sufficient ground to seek methods which would, to some extent, remove the opportunity for fraud in the prosecution of patent applications." Cullen & Vickers, *Fraud In The Procurement of A Patent*, 49 G.W.L. Rev. 110 (1960).

discloses that numerous drug houses have endeavored to enter the tetracycline market. All have been refused with the exception of respondents Cyanamid, Bristol, Squibb and Upjohn.[59]

XI

Alleged Conspiracy Before the Patent Office

Complaint counsel contend that the evidence of record sustains the charge that Cyanamid, Pfizer, and Bristol entered into an agreement or conspiracy to obtain a patent on tetracycline by fraud. The record does show that each of these respondents withheld information from the Patent Office concerning inherent production of tetracycline with Aureomycin. There is no evidence, however, that Bristol did this by agreement or had knowledge that the others were withholding information or were intentionally making false statements.[60] As to Pfizer and Cyanamid, there are

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[59] Soon after tetracycline was placed on the market, Pfizer made a public statement that it did not anticipate licensing others to manufacture tetracycline. (CX 1025, 1070 A-B) At least ten drug houses contacted several of the respondents, including Pfizer, in an attempt to buy it in bulk form for resale to the drug trade. (CX 336, 339, 341-43, 567-70, 571-74, 751-52, 1056-C) In 1954 Upjohn's President reported:

> Bristol tells us that most everyone in the industry has been after Bristol trying to get in on tetracycline.

(CX 942 H, 942 T) The closely-knit tetracycline industry should be compared with the penicillin market which was marked by many competing sellers and effective price competition. In 1948, for example, there were 42 firms competing in sales of penicillin. (RBX 950).

[60] Prior to the dissolution of the second interference Bristol and Squibb were conducting tests to determine whether tetracycline was coproduced with Aureomycin. Since a detective employed in October 1954 by Pfizer's general counsel was tapping the wires of these two concerns, it may be inferred that Pfizer and Bristol probably were not exchanging information on this subject.

circumstances disclosed by the record which point to a possible conspiracy to suppress information concerning inherent production of tetracycline.[61] Although these circumstances *standing alone* might constitute sufficient evidence to find that a conspiracy existed between Pfizer and Cyanamid, weighing all the evidence of record we do not find that complaint counsel has met the burden of proving this charge by substantial, reliable and probative evidence on the record as a whole. We wish to make it clear, however, that we are not finding that the evidence spells out an absence of a conspiracy, but merely that the evidence is inconclusive on this issue. The hearing examiner's conclusion that there was no conspiracy to defraud the Patent Office is based upon an erroneous finding that there was no withholding of information and no misrepresentation by any of the parties. We are in complete disagreement, therefore, with that part of the initial decision dealing with this subject and it is rejected.

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[61] For instance, Cyanamid was aware of Lidoff's interest in inherent production when the exchange of proofs of priority with Pfizer took place during the first interference settlement in January 1954. Lidoff had previously rejected claims in two tetracycline applications (Minieri and Martin-Bohonos) on the ground of inherent production in Duggar and Niedercorn. Also, Edelblute on December 7, 1953, had filed a statement with Lidoff stating that Cyanamid had investigated samples of Aureomycin and had found no tetracycline and that the examiner "need, therefore, have no concern that the product tetracycline is not patentable." This statement was filed in the Boothe-Morton application which was the subject of the settlement negotiations. It would seem that the above information would have been of mutual concern to Pfizer and Cyanamid. Hutz and Edelblute (who respectively represented Pfizer and Cyanamid) deny, however, that they discussed these matters. Edelblute further testified that his December 7 statement was inadvertently omitted from the prosecution papers of the Boothe-Morton application submitted to Pfizer and that Pfizer therefore never saw this.

XII

Alleged Conspiracy to Exclude Others

We are also of the opinion that the evidence falls short of establishing an agreement among all five respondents to exclude competitors from the broad spectrum antibiotic market. Prior to the settlement of the tetracycline patent infringement suit an agreement would hardly have been consistent with the obvious efforts of Pfizer to exclude Bristol, Squibb and Upjohn. After this suit was settled each of the respondents undoubtedly realized that there would be no new entries in the tetracycline market. There is insufficient evidence, however, to prove that they expressly agreed among themselves to exclude others. The record shows, in this connection, that each of the respondents individually desired to exclud additional competitors in the sale of tetracycline. After the settlement of the aforementioned suit an agreement among them to foreclose market entry by other competitors was probably unnecessary.

At the time Cyanamid and Pfizer entered into cross-licensing agreements in January of 1954, these two firms accounted for over 90 percent of the total broad spectrum antibiotic sales with their patented products, Aureomycin and Terramycin. Chloromycetin, produced by Parke, Davis, was the only other broad spectrum antibiotic sold commercially prior to the introduction of tetracycline. For at least two years there had been no effective price competition in the marketing of these products and the prices of all three had remained stable and uniform. By the fall of 1953, both Cyanamid and Pfizer realized that the therapeutic utility of tetracycline was at least equal to that of the other broad spectrums and that tetracycline, if produced and sold commercially, would be fully competitive with Aureomycin and Terramycin. Both firms had good reason to believe that the dominant positions they enjoyed in the broad spectrum

field would be seriously impaired by unrestricted competition in the production and sale of the antibiotic, tetracycline. The entry of new firms could lead to price cutting and a downward trend in the prices of all broad spectrum antibiotics could be expected.

Both Cyanamid and Pfizer had filed applications for a patent on tetracycline and the deschlorination process for its manufacture. Each firm had reason to believe that the other had filed such an application but, prior to the announcement by Heyden Chemical Corporation on September 25, 1953, that it had produced tetracycline by fermentation and had filed a product and process patent application, neither was aware that some other firm was in the tetracycline race. Cyanamid promptly acquired Heyden's Antibiotic Division. There is no evidence that this acquisition by Cyanamid was made as the result of an understanding or agreement with Pfizer as contended by complaint counsel.[62]

After the Heyden acquisition, Cyanamid and Pfizer learned that Bristol had also filed an application for a patent on tetracycline and a fermentation process for its production. They also became aware that Bristol definitely intended to obtain a share of the tetracycline market and that Bristol would sell tetracycline in bulk to other manufacturers.

The record shows, contrary to the hearing examiner's findings, that Cyanamid did not believe that the production and sale of tetracycline could be controlled by the Duggar and Niedercorn patents but, having entered into a cross-licensing agreement with Pfizer, wanted a patent on this product to be obtained by Pfizer. In this connection, Cyanamid had reason to believe that tetracycline product claims in the various patent applications would be rejected by the patent examiner handling the applications on the

[62] See Findings, Paragraph 9.

ground that tetracycline had been inherently produced in the Duggar and Niedercorn processes. The patent examiner had already rejected the fermentation process claims in the Minieri application on the assumption that tetracycline was coproduced in Duggar and Niedercorn[63] and had informed Cyanamid's patent attorney that he considered inherent production as adequate grounds for rejecting product claims. The record shows that the Cyanamid scientists discovered by December of 1953, prior to the date of the cross-licensing agreements, that coproduction of tetracycline did occur in the manufacture of commercial Aureomycin. Instead of taking the position before the Patent Office that tetracycline was unpatentable, Cyanamid entered into the cross-licensing agreement with Pfizer, again denied that tetracycline was coproduced with Aureomycin, and withheld information indicating that such coproduction occurred. Cyanamid's cooperation with Pfizer during the second interference before the Patent Office further demonstrates that Cyanamid did not believe that it could control the production and sale of tetracycline by means of its Aureomycin patents. The hearing examiner has inconsistently held in this connection that Cyanamid knew that it unilaterally possessed the power to exclude other manufacturers of tetracycline but that Cyanamid's cooperation with Pfizer during the second interference was "logical" because Cyanamid lacked this power. (Initial Decision, pp. 26, 36)[64]

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[63] Malcolm, President of Cyanamid, testified that he was aware of this rejection and had discussed it with Cyanamid's patent attorney. He later changed his testimony and claimed that he had no knowledge whatsoever of this rejection or the reason therefor. (Tr. 5477, 5486)

[64] Malcolm testified that he was "extremely happy" when he learned that the patent examiner had rejected all product claims because he then knew that Cyanamid would be able to control tetracycline under its Duggar patent. However, Cyanamid's patent attorney, Edelblute, who worked closely with Malcolm, stated with respect to the patent examiner's ruling, "This is, of course, a very unexpected

From a review of the evidence relating to Cyanamid's conduct during the Patent Office proceedings, we have no doubt that this respondent wanted Pfizer to obtain a patent on the product tetracycline in order that other firms could be excluded from the broad spectrum market. Cyanamid would, as its patent officials stated, "rather pay royalties to a bona fide patentee than see the pharmaceutical business in which it has a major interest ruined by irresponsible price cutting". (CX 12, p. 115).

Insofar as Pfizer is concerned, the statements made by officials of this firm clearly disclose that after entering into the cross-licensing agreement with Cyanamid it intended to exclude all other firms from the tetracycline market in order to avoid price competition on this product. The importance Pfizer attached to a controlled tetracycline market is graphically demonstrated by the methods it employed to obtain a patent on this product.

XIII

The Pricing Practices Charge

We now turn to the charge that the respondents engaged in illegal pricing practices. The facts establish (1) that all respondents, Pfizer, Bristol, Squibb, Upjohn and Cyanamid, conspired with one another to fix and stabilize tetracycline prices.

(The published prices to retailers of broad spectrum antibiotics sold by Cyanamid, Pfizer, Bristol, Squibb and Upjohn during the period relevant to this proceeding are set forth in the following tabulations):

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and disturbing outcome of the interference" . . . (RACX 878) He also informed Malcolm, at the time, that he had requested Cyanamid's laboratories to make investigations which would help Pfizer overcome the assumption of inherent production upon which the patent examiner based his ruling. Another Cyanamid official wrote, at the time, that he hoped the news of the rejection of the tetracycline claims would not spoil Malcolm's vacation. (RACX 879)

1951—1958

TABULATION OF PRICE TO RETAILER OF TETRACYCLINE, AUREOMYCIN AND TERRAMYCIN

	Cyanamid Achromycin	*Pfizer Tetracyn*	*Bristol Polycycline*	*Squibb Steclin*	*Upjohn Panmycin*	*Cyanamid Aureomycin*	*Pfizer Terramycin*
Capsules							
100 MG 25's	$ 3.61	$ 3.61	$ 3.61	$ 3.61	$ 3.61	$ 3.61	$ 3.60
100 MG 100's	13.77	13.77	13.77	13.77	13.77	13.77	13.77
250 MG 16's	5.10	5.10	5.10	5.10	5.10	5.10	5.10
250 MG 100's	30.60	30.60	30.60	30.60	30.60	30.60	30.60
Intramuscular							
100 MG Vial	.94	.94	.94	.94	.94		.94
Intravenous							
250 MG Vial	1.62	1.62	1.62	1.62	1.62	1.62	1.62
500 MG Vial	2.91	2.91	2.91	2.91	2.91	2.91	2.90
Ped. Drops							
100 MG/cc 10cc	1.47	1.47	1.47	1.47	1.47	1.47	1.47
Oral Susp.							
250 MG/5cc 1 oz.	2.54	2.55	2.54	2.54	2.55		2.55
Syrup							
125 MG/5cc 2 oz.	2.54	2.55	2.54	2.54	2.55		2.55
125 MG/5cc 16 oz.	18.36	18.36	18.36		18.36	18.36	18.36

RESPONDENTS' PRICE TO RETAILER OF COMBINATION PRODUCTS

Tetracycline-Vitamins

Company	*Product*	*Dosage Form*	*Package Size*	*Retail Price*
Cyanamid	Aureomycin SF	250 mg cap.	16's	5.28
Cyanamid	Achromycin SF	250 mg cap.	16's	5.28
Pfizer	Terramycin SF	250 mg cap.	16's	5.28
Pfizer	Tetracyn SF	250 mg cap.	16's	5.28
Cyanamid	Aureomycin SF	250 mg cap.	100's	31.60
Cyanamid	Achromycin SF	250 mg cap.	100's	31.60
Pfizer	Terramycin SF	250 mg cap.	100's	31.60
Pfizer	Tetracyn SF	250 mg cap.	100's	31.60
Cyanamid	Achromycin SF	Oral susp.	2 oz.	2.64
Pfizer	Tetracyn SF	Oral susp.	2 oz.	2.64

Tetracycline-Antihistamines

Cyanamid	Achrocidin	125 mg tablets	24's	4.26
Bristol	Tetrex APC	125 mg cap.	24's	4.26
Pfizer	Tetracydin	125 mg tablets	24's	4.26
Cyanamid	Achrocidin	125 mg tablets	100's	17.04
Bristol	Tetrex APC	125 mg cap.	100's	17.04
Pfizer	Tetracydin	125 mg tablets	100's	17.04

Tetracycline-Nystatin

Cyanamid	Achrostatin	250 mg cap.	16's	5.60
Squibb	Mysteclin	250 mg cap.	16's	5.60
Upjohn	Comycin	250 mg cap.	16's	5.60
Cyanamid	Achrostatin	250 mg cap.	100's	33.50
Squibb	Mysteclin	250 mg cap.	100's	33.50
Upjohn	Comycin	250 mg cap.	100's	33.50
Squibb	Mysteclin	125 mg cap.	100's	17.23
Upjohn	Comycin	125 mg cap.	100's	17.23

Opinion of the Commission

In reviewing that part of the initial decision dealing with this phase of the case, we find the following errors on the part of the hearing examiner:

(1) He erred in assuming that it would have been illogical for any of respondents to have fixed prices prior to the settlement of the tetracycline patent infringement suit.

(2) He erred in finding that there was extensive and substantial price competition in the NPA[65] and CCS[66] hospital markets and in the Federal market.[67]

(3) He erred in finding that the totality of the evidence relating to the pricing practices of any of the respondents warrants an inference that there was no conspiracy among any of them to fix prices.

(4) He erred in considering the evidence relating to pricing separately and apart from the other circumstances of record.

(5) He erred, finally, in drawing the inference from the shift in market shares that there was price competition among respondents.

1. The hearing examiner declared:

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[65] Non profit association consisting of privately owned hospitals and clinics, whether or not operated for profit; hereinafter referred to as NPA.

[66] City, County and State hospitals consisting of tax supported hospitals operated by municipalities, cities, countries and states; hereinafter referred to as CCS.

[67] The Federal market includes such federal agencies as GSA, VA and Defense Department facilities; hereinafter referred to as the Federal market.

> It seems highly improbable that persons bitterly fighting each other over a patent infringement matter would at the same time enter into a conspiracy or agreement to fix the prices of the same product which was the subject matter of the patent, and which Pfizer was doing everything within its power to keep Bristol, Squibb and Upjohn from marketing. (Initial Decision pp. 143-144)

Thus the hearing examiner inferred that a price fixing agreement would hold no attraction to these alleged participants. This reasoning not only ignores facts of record but reflects a lack of understanding of the close relationship which existed among respondents.

The Supreme Court has often noted that it is not necessary for the Government to fix with exactitude the time when a conspriacy was conceived. In *United States* v. *United States Gypsum Co., et al.*, 333 U.S. 364, 393 (1948), the Court held:

> We do not attempt to fix a date when the conspiracy was first formed. At least the declarations which we have quoted were made with the purpose of advancing a plan which ultimately eventuated in the licenses of 1929.

See also: *United States* v. *Masonite Corp.*, 316 U.S. 264 at 275 (1942).

It is sufficient to note here that the conspiracy as to all of the respondents was in effect at least as early as 1955—thus during the pendency of what Pfizer terms its "hard fought patent infringement litigation" [68] against Bristol, Squibb and Upjohn.

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[68] Pfizer's Answering Brief, Part II p. 24.

In a sense the argument that the patent infringement case is "inconsistent with any possibility" [69] of Pfizer's involvement in a price fixing conspiracy is simply a more poignant variant of the old and rejected theme that the Government must prove that a price fixing scheme permeated through every facet of corporate activity and every related corporate transaction. In rejecting such premises, the District Court noted in *United States* v. *Minneapolis Electrical Contractors Association,* 1952-53 Trade Cases, Par. 67,488 (D.C. Minn. 1953)

> . . . [T]hat this scheme was not successful in all of its ramifications is no defense, and that at times even the conspirators did not in every transaction comply with all the mandates of the planners is not controlling as to whether the conspiracy was launched . . . and participated in.

See also: *U.S.* v. *Trenton Potteries Co.,* 273 U.S. 392, at 402 (1927).

Indeed, in contrast to respondents' arguments which assume an unvarying monolithic consistency within a corporation, it is more probable, as contended by many high echelon executives, that today's corporation is a hydra-headed affair in which policies promulgated by the sales department may sometimes be at variance with directives

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[69] Pfizer's Answering Brief, Part II p. 24.

Moreover, in *United States* v. *The Singer Manufacturing Company,* 31 U.S. L. Week, 4674 (U.S. June 17, 1963), the Court rejected "as a question of law, the . . . inference that the attitude of suspicion, wariness and self-preservation negated a conspiracy". Previously in *United States* v. *Line Material Co.,* 333 U.S. 287, 297 (1948), the Court found a price fixing conspiracy among patent licensees many of whom actively opposed the plan to which they were required to accede as the price of the patent license.

from the Board of Directors.[70] Indeed, in instances where it has been *proven* that subordinates were involved in price fixing criminal conspiracies, one of the defenses often urged with sincerity and truthfulness for exculpation of their corporate superiors is that the price fixing policy was inconsistent with other announced corporate directives and policies promulgated by the Board of Directors or senior executive officers. Even in theory, we are not completely convinced that, within a single corporate empire, price fixing and patent infringement suits are mutually exclusive alternatives. Moreover, this issue of a single unified posture versus conflicting corporate practices need not be resolved by speculation; for the record of this case established that during the existence of the hard fought litigation the bitterness of the courtroom never affected the continuing cordiality between the marketing divisions of at least two of the litigants. Thus, at the very height of the infringement suit in June, 1955, Pfizer and Upjohn were careful to exchange precise and detailed price information. On June 2, 1955, Pfizer wrote:

> Under separate cover we are sending you a complete new set of price pages for your Pfizer Laboratories

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[70] The Broady incident corroborates our analysis that agents or employees sometimes take positions repugnant to some other announced company policies with or without authorization. From December 1954 to February 1955, Pfizer admits that "Broady was a private investigator who had been employed by Pfizer". *Pfizer's Answering Brief,* Part II, page 23. Broady was paid $60,000.00 for a three month security investigation; during this time he tapped the wires of Squibb, Bristol and other parties, for which he was subsequently convicted. McKeen, now President of Pfizer, testified that the wire tap was unauthorized and thus, assuming his veracity, his testimony established another instance in which Pfizer's employees or agents blithely ignored corporate policy and exercised individual initiative in a highly questionable manner. See also Bristol's Answering Brief, Appendix 1—12, Excerpts from the Record on Appeal in the Broady Wiretap Case, *The People of the State of New York* v. *John G. Broady,* 6 A.D. 2d 674 (1st Dept. 1958).

loose-leaf catalog. Kindly remove all pages from your present cover and insert this refill.

When new products are added to our line, you will receive announcements in the form of "Pfizer Scripts", a new series of price and product information folders. These pages when inserted in the proper sequence will keep your copy of our price list up-to-date.

Please continue to send me new product and price information on your line so that my copy of your catalog will always be current.

Thank you for your cooperation.

Very truly yours,

H. H. KIBBE
Manager, Pricing Department

(CX392)

On June 9, 1955, Upjohn replied as follows:

Thank you very much for sending us a copy of the ~~new Pfizer Laboratories loose-leaf~~ price schedule. We will also look forward to receiving the "Pfizer Scripts" and will see that they are inserted promptly to keep your price list up to date. Information folders should be directed to my attention.

We have mailed you a copy of the Upjohn catalog, and your name has been placed on our mailing list so that you will receive reprinted pages as they are prepared.

Very truly yours,

THE UPJOHN COMPANY
H. E. Shepard

(CX393)

Admittedly the simple exchange of price information can be a neutral factor in the proof of a conspiracy. But as was stated by the Supreme Court in *Sugar Institute* v. *United States,* 297 U.S. 553, 600, in weighing the relevance of the exchange of such trade statistics "*each case demands a close scrutiny of its own facts*". See also: *Tag Manufacturers, et al.* v. *Federal Trade Commission,* 174 F. 2d 452 (1959). Upon scrutiny of the facts of each case, the dissemination of pricing information plus other anti-competitive and conspirational conduct could tip the scales for a finding against respondents. Numerous principles announced in *Morton Salt Company* v. *United States,* 235 F. 2d 573, 576 (10th Cir., 1956), are applicable in the instant case. There the Court noted:

> . . . They [defendants] produced expert witnesses who testified that since all salt is virtually alike and the major consumers are generally informed buyers a fraction of a cent difference in price will cause a major shift in business; thus by operation of the laws of economic behavior the tendency is to highly uniform prices in a market area. Nevertheless, it seems clear that the free disclosure to each other of pricing data and proposed bids speeded the achievement of uniform prices. Appellants urge otherwise because they say the information was readily accessible from other trade sources. While the publication of prices bid to government agencies and a spy system would undoubtedly reveal partial pricing information on competitors, some of the evidence shows extensive information was not easily acquired.
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> * * *
>
> In the instant case we have more than a dissemination of statistics, there was a frank exchange, between competitors controlling 95% of the market, of all the de-

tails of a fairly complicated pricing system. *Certainly the exchange is a factor appropriately considered in determining the existence of a conspiracy.* (Emphasis added)

We note that on the facts of this case, there is no evidence of a beneficial industry-wide purpose to be served by the exchange of the information; nor is there evidence of chaos in the tetracycline industry to suggest the necessity for exchange of such information. Cf. *Appalachian Coals, Inc., et al.* v. *United States,* 288 U.S. 344 (1933).

In the instant case, we find that between the competitors controlling 100% of the market, there was an exchange of the details of a reasonably complicated pricing, manufacturing and distribution system. As in *Morton Salt* such exchange of information made it unlikely for any of the respondents to inadvertently engage in active price competition.

Also disregarded is the contemporaneously expressed dissatisfaction with the vigorous competition which had broken out in previous antibiotic markets, *e.g.,* penicillin. As hereinabove found, respondents wanted tetracycline to be controlled by patent and as discussed herein each of them desired to avoid price competition in the sale of this product. Early in these proceedings, the entrance of Bristol, Squibb and Upjohn was opposed by Pfizer and Cyanamid. These two firms feared that additional entries in the market would cause a price decline. But Bristol, Squibb and Upjohn wished to take advantage of the existing price structure. Any ill will felt by Bristol, Squibb and Upjohn would probably yield to a profit motive. In these circumstances, on the basis of our cumulative experience and judgment, a price agreement would have been just as logical as engaging in price cutting or any other form of price competition, adversely affecting the price level of

tetracycline. Thus, disagreement on other matters, including the patent infringement case, is not dispositive of the price fixing charge.

2. Nor does the record support the hearing examiner's finding of extensive or substantial price competition in the hospital and Federal markets. Clearly the existence of the congruent pricing practices of respondents in these markets does not support the hearing examiner's conclusion that there was "no conspiracy to fix prices" among Pfizer, Cyanamid, Bristol, Squibb and Upjohn. While we think this evidence, when viewed separately from other facts of record, may be consistent with an inference of individual action, upon considering the record as a whole, we find it more consistent with an inference of agreement.

We find that all respondents deliberately avoided any form of competition which would materially affect the price level of broad spectrum antibiotics. It may be that respondents to some extent competed among themselves in the broad spectrum market by developing new products, by use of detail men, by use of "free goods", and by other methods.[71] However, it is clear that each of them was careful not to compete in any manner which would cause a significant decline in the publicly established NPA price, because of the competitive effects which this would cause in the retail market. (See infra.)

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[71] "The fact that there existed competition of other kinds between the various Plymouth dealers, or that they cut prices in bidding against each other, is irrelevant. This point is touched upon in the recent case of *United States* v. *American Smelting & Refining Company*, D.C. S.D. N.Y. 182 F. Supp. 834." *Plymouth Dealers' Association of Northern California* v. *United States*, 279 F. 2d 128, 132 (9th Cir., 1960).

Moreover, the Supreme Court has held that the existence of such competition does not preclude a finding of agreement to fix prices. See *Federal Trade Commission* v. *Cement Institute, et al.*, 333 U.S. 683 (1948); *National Lead Company, et al.* v. *Federal Trade Commission*, 227 F. 2d 825 (7th Cir., 1955).

Approximately 75 percent of the respondents' total sales of tetracycline were made to wholesalers and [Correction per Comm. Order of 1/3/64.] retailers, who resold to the consuming public. The uniform pricing found to exist in this retail market, when considered apart from the pricing practices in other markets, might be deemed to have resulted from independent decisions of respondents not to change their prices. Cf. *Pevely Dairy Co.* v. *United States,* 178 F. 2d 363 (8th Cir., 1949). To be sure, each of them realized that a price reduction would promptly be met; so it was unlikely that any firm could sell its fungible products at a higher price.

As indicated in Finding 31, despite the purchasing power of a single hospital, the market to retailers was the largest one to which respondents sold. Obviously they could not afford to cut the price to the hospital market and not cut the price to the retail market without putting in jeopardy their largest source of revenue. And the very fact that the price to retailers remained uniform during the period relevant to this action is significant in this proceeding.

THE NPA MARKET

There was a peculiar "follow the leader" relationship existing between the price to retailers and the publicly known price at which tetracycline was sold to NPA and CCS hospitals. Respondents concede that the price to NPA hospitals by tradition has been the same as the price to the retail trade, and the evidence shows that a direct price cut to NPA hospitals would result in immediate pressure to cut the price to the retailer. As in the retailer market, a price cut in the NPA hospital market by any one of the respondents would have been self-defeating, but, unlike the larger but dispersed retailer market, the NPA hospitals

were able to exert pressure for price reductions. Also, unlike the retailer, hospital pharmacists were usually not required to purchase tetracycline by brand name. Because of this method of buying, there was a great incentive for respondents somehow to reduce the price in order to capture large spot sales. Instead of cutting the published NPA price, however, each of the respondents offered "free goods" as an inducement to obtain the business of these institutions. The hearing examiner has found in this connection that "free goods" were furnished to NPA hospitals "as a means of effecting a price reduction on negotiated sales". We draw a different inference. "Free goods" were used by the respondents as a concealed rebate device in lieu of direct price reductions to prevent a general price reduction in this market and in the traditionally related retail or prescription market. If the evidence relating to the practice of furnishing "free goods" is viewed out of context, it can, of course, be argued that the similar behavior of Pfizer, Cyanamid, Bristol, Squibb and Upjohn in using this device did not stem from actual agreement but resulted from individual decisions not to engage in direct price competition.

But we find that the evidence concerning the common use of the "free goods" device is persuasive circumstantial evidence of agreement to stabilize prices by Pfizer, Cyanamid, Bristol, Squibb and Upjohn. It is clear that these named respondents have adhered to a policy of refraining from direct price competition in the NPA market in order to protect the price level in the retail market.

The CCS Market

In the CCS hospital market, as in the NPA, the respondents were faced with power buyers, and the incentive to reduce prices again was considerable. Here also there was a danger that reduction of the CCS price might spread to the prescription market. Respondents solved this problem by refusing to deviate from their published prices in direct

bids to CCS institutions and by limiting the form of price competition to varying bids submitted by their dealers (retailers and wholesalers). In this connection, the retailers' purchase prices, and after May of 1955, the wholesalers' purchase prices, were higher than the published CCS prices. To enable their dealers to bid for CCS business, the respondents uniformly granted a ten percent handling allowance to compensate the dealers for their services. Although respondents did not usually encourage price competition among dealers, a dealer could pass on all or any part of their handling allowance to the CCS buyer. By using this method of selling, respondents Pfizer, Cyanamid, Bristol, Squibb and Upjohn, were able to avoid direct price competition among themselves, and to obscure the origin and extent of any price reductions made to CCS institutions. Thereby they protected their published prices; and with respect to this group of power buyers (CCS), limited price reductions to a ten percent discount from list prices.[72]

FEDERAL MARKET

With respect to the Federal Market, the record shows that, except for sales to the Veterans Administration during a fourteen month period (June 6, 1955 to July 30, 1956), there were some variations in the prices at which tetracycline was sold to the various agencies.[73]

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[72] Cf. *Plymouth Dealers' Ass'n. of Northern Cal.* v. *U.S.*, 279 F. 2d 128, 134 (9th Cir., 1960): "This [a fixed uniform price list] established as a matter of actual practice one boundary of 'the range within which sales would be made'. Socony-Vacuum Oil Co., supra, 310 U.S. at page 222, 60 S. Ct. at page 844. This was 'a factor which prevents the determination of [market] . . . prices by free competition alone.' Id., 310 U.S. at page 223, 60 S. Ct. at page 844."

[73] Moreover, our Finding 37 notes that during this period there was such an extraordinary identity between the respondents' prices that at one point the VA was forced to draw the name of the winning bidder out of a hat.

This departure from the pricing patterns in other markets can be accounted for by efforts of the federal agencies to bring about competitive prices. It is also quite probable that respondents realized that price uniformity in sales to the government might bring about an antitrust investigation. It is significant, however, that in sales in this market the deviations from the published price were not so great as to cause a substantial price decline. As late as 1958, the price to the federal government had not reached the lower level at which respondents had sold tetracycline to the Canadian government in 1955.

3. From our review of the pricing practices of respondents, we conclude that there was an intentional and deliberate avoidance of effective price competition. By use of the aforementioned devices and others, including the adoption of uniform package sizes, resale price maintenance, avoidance of price competition among different dosage forms, and refusal to give quantity discounts, respondents have been able to maintain substantial price uniformity in the sale of tetracycline. The question presented, therefore, is whether all of the respondents adopted these devices to facilitate the maintenance of price uniformity solely by individual decision, whether they did so by agreement, or

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And cf. *National Lead Company* v. *Federal Trade Commission*, 227 F. 2d 825, 833, 834 (7th Cir., 1955), where the Court stated:

> Furthermore, it is clear that a finding of unbending price uniformity is not a requisite of a finding of conspiracy to control prices, but that any device which has the purpose and effect of fixing prices to consumers is an illegal restraint of trade—*United States* v. *Socony-Vacuum Oil Co.*, 310 U.S. 150, 222-3, and 'it is not important that the prices fixed were uniform and inflexible'. *Allied Paper Mills* vs. *Federal Trade Commission*, 168 F. 2d 600, 607 (CA-7). The same principle applies to evidence that petitioners' bids on government contracts frequently were not uniform. We cannot say that the inference of agreement cannot stand in the face of such evidence.

finally whether they did so in a setting such that their acts violated §5. A determination of this issue can be made only by considering all the relevant facts.

The hearing examiner states:

> Of course it is clear that uniformity of price is an essential first step in the circumstantial chain necessary to infer agreement. Without such substantial uniformity, it would be difficult even to contend that a price-fixing conspiracy existed. *The confusion here arises in treating such uniformity as the only circumstance needed.* As shown above, this is fallacious. Given other persuasive circumstances ("plus factors") from which an agreement is inferable, together with price uniformity, the test has been met. The uniformity of price is but one circumstance, the first step in a chain of proof. Standing alone it cannot lead to an inference of agreement. [Emphasis added.]

But it is obvious from counsel's proposed findings that *they do not rely solely on the showing of substantial price uniformity to sustain the allegation of price fixing.* The hearing examiner acknowledges this fact himself in that section of the initial decision entitled "Miscellaneous Items of Evidence Concerning Prices".[74] But he rejected these 'miscellaneous items' finding each document by itself inconclusive; and any inference to be drawn therefrom he held explained away by oral testimony.

In such a context, he has concluded that while "a price-fixing conspiracy may be inferred from circumstantial evi-

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[74] In referring to this evidence the examiner states on page 168: " . . . based upon certain items of documentary evidence, primarily intracorporate memoranda during the period of the litigation, counsel supporting the complaint *propose numerous findings* to the effect that Pfizer, Cyanamid, Bristol, Squibb and Upjohn agreed to fix prices at that time. The items of evidence and exhibits *frequently cited and relied upon* by counsel supporting the complaint are as follows:" [Emphasis added.]

dence and does not have to be proved by direct evidence of agreement, it is well settled that uniformity of prices, even though known to each trader, while one of the pertinent circumstances standing alone does not establish such an agreement." See *Pevely Dairy Co.* v. *U. S., supra;* but cf. *C-O Two Fire Equipment Co., et al.* v. *U. S.,* 197 F. 2d 489 (1952). Thus, the examiner concluded that the allegedly neutral factor of price uniformity was not bolstered by other believable evidence. At best, the hearing examiner concluded that the case presented by complaint counsel amounted to "conscious parallelism" and this, he said, has clearly been held to be no offense under the Sherman Act.

Our view of this matter requires some preliminary discussion. And in our opinion " . . . whether an unlawful combination or conspiracy is proved is to be judged by what the parties did not what they said". *U.S.* v. *Parke, Davis & Co.,* 362 U.S. 29, 44 (1960). Facts, not semantic labels, are the criteria of this Commission.

Preservation of competition is the main thrust of Section 5. Basically under that law we are concerned with the commercial impact of techniques employed by firms in maintaining or increasing their standing in the market place. In today's economy there are many industries which are characterized by "price leadership". Characteristically, in such a market, each firm only changes its action when the "price leader" alters its course. On the other hand, both the nature of the product and profit considerations may create a situation where the sellers are more or less equal; and with no specific leader present and with no communication and no agreement, tacit or otherwise, each firm may adjust its actions to the other so that a type of happy symbiosis exists. Cf. *American Tobacco Co.* v. *U. S.,* 328 U.S. 781 (1948). Apparently the hearing examiner has concluded that the tetracycline market was an example of the aforementioned condition. Our view of the facts is different. And the power of this Commission

to reverse a fact finding decision by a hearing examiner is substantially broader than the power of Federal Appellate Courts to reverse the findings of fact of Federal District Trial Courts. That this is so has been carefully articulated by the Supreme Court.[75] In *F.C.C.* v. *Allentown Broadcasting Corp.*, 349 U.S. 358, 364 (1955), it stated:

> The Court of Appeals . . . attitude goes too far. . . . It seems to adopt for examiners of administrative agencies the 'clearly erroneous' rule of the Fed. Rules Civ. Proc., 52(a), applicable to courts. . . . The Federal Communications Act gives the Commission the power of ruling on facts and policies in the first instance.

Yet even under the more limited factual review power exercised by the Supreme Court, decisions of lower trial courts have been reversed under the "clearly erroneous" doctrine. See *United States* v. *The Singer Manufacturing Co.*, 31 U.S. L. Week 4674 (U.S., June 17, 1963).[76]

Thus the written and even the spoken word are always susceptible to varying interpretations and the equivocal nature of each separate document and each separate utterance may be heightened when it is placed *in vacuo*. From our experience we know that finding one document or even a series of documents spelling out in detail the existence

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[75] "But the Supreme Court in Universal Camera made it clear that the responsibility for decision is still on the Board or Commission." Jaffe, *Judicial Review: Question of Fact.* 69 H. L. Rev. 1020, 1038 (1956).

[76] "The evidence here, including many findings of the trial court, clearly compels the conclusion that the parties' concerted activities were motivated by a common purpose, and the court's conclusion to the contrary must be regarded as clearly erroneous. *United States* v. *United States Gypsum Co., supra;* see *Pacific Portland Cement Co.* v. *Food Mach. & Chem. Corp.*, 178 F. 2d 541 (C.A. 9th Cir., 1949)." 31 U.S. L. Week at 4680.

of a conspiracy is a rare occurrence. Even more unusual is the conspiracy proven by the sworn testimony of the conspirators. But the law does not tell us that we must by some psychic tour de force, rip bare the collective psyches of respondents and reveal every factual detail of a conspiracy with precise clarity. Nor, on the facts of this case do we have to speculate whether the general existence of commercial peace in an oligopoly is a believable coincidence or whether, by itself, that condition creates the presumption of an agreement not to wage war. As to these respondents these questions have been answered by the record in this case. We find that the lack of aggressive tactics on the part of Pfizer, Cyanamid, Bristol, Squibb and Upjohn stands out starkly against a backdrop of conspiratorial contact, proven by direct and circumstantial evidence, culminating in the quiet smothering of competition. *Although the record reveals individual pieces of evidence susceptible to varying inferences the total impact of these respondents' conduct leads inescapably to the conclusion of a conspiracy in restraint of trade.*[77]

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[77] As indicated, the ruling of the hearing examiner was to the contrary. But we find the language of *U.S.* v. *U.S. Gypsum Co., et al.*, 333 U.S. 364, 395 (1947) especially appropriate here:

> The government relied very largely on documentary exhibits, and called as witnesses many of the authors of the documents. Both on direct and cross-examination counsel were permitted to phrase their questions in extremely leading form, so that the import of the witnesses testimony was conflicting. On cross-examination most of the witnesses denied that they had acted in concert in securing patent licenses or that they had agreed to do the things which in fact were done. Where such testimony is in conflict with contemporaneous documents we can give it little weight, particularly when the crucial issues involve mixed questions of law and fact.

This holding was recently reiterated and confirmed by the Third Circuit:

> The appellee argues that the findings may not be disturbed unless clearly erroneous. See Rule 52(a), 28 U.S. C.A. We do

Merely because the documents in this case do not amount to a signed and sealed written contract to fix prices does not mean that they may be dismissed as of no probative weight. Certainly, the firms who authored them may offer an explanation. But explanation is not the equivalent of innocence. And so we turn to an examination of that documentary evidence supporting our conclusion that respondents have entered into a conspiracy violative of Section 5.

4. We begin with the evidence relative to the conduct of Bristol, Squibb and Upjohn at the time the two latter firms entered the tetracycline market. These firms hoped to acquire licenses under any patent Pfizer might receive. Bristol was fully aware, however, that Pfizer would never grant a license to a firm that would cut prices, and Pfizer regarded Squibb as one of the worst price cutters in the industry (CX 1056 C). Certainly Pfizer would be more favorably disposed to licensing firms that would not destroy the value of its patent by extensive price cutting. Taking into consideration these circumstances, the only

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not agree that the "clearly erroneous" test is applicable on the present appeal. The findings of fact made by the trial court were based on a comparison of the exhibits, and uncontradicted testimony of a single witness, and the inferences drawn from the evidence. It has been uniformly held by this Court, and others, that under these circumstances the findings of fact are reviewable on appeal, free of the impact of the said rule. *Sears, Roebuck and Co.* v. *Johnson,* 219 F. 2d 590, 591 (3d Cir., 1955); *Benrose Fabrics Corp.* v. *Rosenstein,* 183 F. 2d 355, 358 (7th Cir., 1950). Accord *Merchants National Bank and Trust Co.* v. *United States,* 246 F. 2d 410, 417 (7th Cir. 1957), cert. den. 355 U.S. 881 (1957), reh. den. 355 U.S. 920 (1958); *In Re Kellett Aircraft Corp.,* 186 F. 2d 197, 200 (3d Cir., 1950); *Orvis* v. *Higgins,* 180 F. 2d 537, 539, 540 (2d Cir., 1950), cert. den. 340 U.S. 810 (1950). The argument advanced by the appellee is without merit." (*Surgical Supply Service, Inc. v. Sol H. Adler,* Slip Opinion, 3d Cir.—June 28, 1963, Pp. 4-5.)

reasonable inference to be drawn from the following documentary evidence is that Bristol insisted on its two bulk customers adhering to the established prices.[78]

Numerous intra-corporate memoranda prepared by Squibb's sales officials demonstrate that insofar as its tetracycline products were concerned, Squibb suddenly became obsessed with a desire to correct its "loose business practices" and to live down a reputation as a price cutter. On September 17, 1954, the day Squibb began marketing tetracycline under the trade name Steclin, the Squibb Manager of Marketing, Heberger, sent the following message to all representatives of his firm:

> The Steclin pricing schedule must be adhered to strictly. Steclin is not to be involved in any special terms used to meet competitive situations on other antibiotic products.
>
> Steclin should be sold direct in every case possible. When a handling credit situation must apply we will arrange 10% handling credit only on a drop shipment basis.

---

[78] The testimony of officials of Bristol, Squibb and Upjohn, together with documents obtained from these firms, show that at the time Squibb and Upjohn began buying tetracycline in bulk from Bristol there was at least a tacit understanding among these firms that they would sell tetracycline at the then existing price level. Bristol initially sold in bulk at $1,000 per kilogram but promised to lower this price to $350 in order to give Squibb and Upjohn a 3 to 1 profit ratio between their cost and the market price. Such assurance could have been given only if there was an understanding that all would adhere to the established price. That the ratio between cost and market prices was to be maintained and that the CCS price was to be uniform is evident by a memorandum prepared some three years later by a Squibb official. The following comment was made therein with respect to a low bid by Upjohn to a CCS institution: "Now since Upjohn buys their tetracycline from the same source as Squibb, either they are getting it at a better price or Bristol should be informed of this bid." (CX 252)

> We have had some reports of competitive prices of Tetracycline products at variance with public schedules. Please send along to your branch promptly any specific information regarding such deviations you run into on your territory.
>
> (CX 204)

The following month Heberger stated that "Squibb cannot be officially connected with any price maneuver on Steclin which can be construed as cutting the price" and that "There can be no compromise with our position of maintaining prices on this product." (CX 207) And in November he said, "[I]t is our fixed policy not only to avoid price cutting on Steclin but to avoid any practice which might lay us open to such an accusation." (CX 210)[79]

Of even greater significance than the aforementioned memoranda are letters written by Squibb and Upjohn concerning an order obtained by Squibb from Los Angeles County Hospital. On April 27, 1955, Heberger wrote:

> I was disturbed to learn that we were the successful bidder to Los Angeles County because we bid on Tetracycline 250 Mg. capsules $22.49 per 100, less 2% discount. It is nice to get a Steclin order finally from Los Angeles County *but I have my fingers crossed, anticipating certain reactions to what we did, which may not be good.* (Emphasis added) (CX 213)

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[79] Memoranda prepared three years later show that there was no deviation in Squibb's policy of avoiding price competition. In a memorandum prepared on October 22, 1957, a Squibb official stated that Squibb would be competitive on penicillin and streptomycin products and that it would be "willing to meet or beat anything Pfizer quoted." (CX 250) This memorandum further stated, "We cannot do this on the broad spectrum, but on our own Penicillin and Streptomycin products we can." Evidence of this type showing that respondents themselves were aware of the fact that tetracycline prices were non-competitive is not consistent with the examiner's finding of extensive and substantial price competition.

Opinion of the Commission

On April 6, 1955, Upjohn's Los Angeles, California branch manager wrote to Upjohn's Price Determination Department Manager, as follows:

> As requested, we are enclosing the results of the bids at Los Angeles County Hospital:
>
> 864 Tetracycline Caps. 250 Mg. went as follows:
>
> | | | |
> |---|---|---|
> | Pfizer | $22.49 | 2% 15th proximo |
> | Squibb | $22.49 | 2% open |
> | Lederle | $22.49 | net |
> | Bristol | $22.49 | net |
>
> Homer Hammond feels Squibb will get the bid with an open 2% time limit . . .
>
> * * *
>
> We will forget that one. On the Panmycin it looks like Squibb scuttled our ship. *I wonder if Bristol will complain to them as they did with us.* [Emphasis added] (CX 473)

These letters are evidence of an understanding among the three firms (Bristol, Squibb and Upjohn) that they would not deviate from established prices. Moreover, they show that Bristol was trying to keep Squibb and Upjohn in line. There is also evidence in this connection that Squibb was keeping track of Bristol's deviations and had obtained from Bristol explanations for each of them. A document in Squibb's files entitled "*Bristol* Price Variations" (emphasis added) listed the names of eight institutional accounts, the price reduction or "free goods" deal made to each and the reason therefor. (CX 308) For example, the Squibb list on Bristol's price variations shows that a bid of $19.76 by Yants Pharmacy of Bakersfield, California of Bristol products to the State of California, was "*unauthorized*"; that a one-for-one "free goods" deal

to Jefferson Hospital of Philadelphia was a *"mistake"*; and that Mark Surgical Supply for University Hospital of Augusta, Georgia, received a ten percent discount because it was a "problem account". It is, of course, possible that Yants Pharmacy could have informed a Squibb representative that Bristol had not authorized it to bid $19.76. It is unlikely, however, and we do not believe that Jefferson Hospital informed Squibb that a reported "free goods" deal was a "mistake" or that Mark Surgical Supply for University Hospital told Squibb that it was a "problem account". (There is nothing in the record to indicate that Squibb considered Mark a problem account). It is also unlikely that the writer of the document was guessing here since elsewhere in the document he used the word "probably" to indicate doubt as to the accuracy of an explanation. The Squibb document also states that Bristol's "cost of free goods and samples" during a seven month period was 7.5 percent. It would also seem unlikely that Squibb could obtain from its own field personnel such complete information as to Bristol's total sales and its "cost of free goods and samples" that it could determine precisely (to one-half of one percent) the cost of the latter or that it would even attempt to make such a determination. We are convinced, for the foregoing reasons, that the explanation for Bristol's "variations" and the information as to the "cost of" free goods and samples were obtained by Squibb from Bristol.

Cyanamid's and Pfizer's involvement in the price-fixing conspiracy is manifest in the following documents.

On May 27, 1954, the Cyanamid Chicago Regional Manager sent the following message to his sales manager:

> *Apparently Pfizer and Roerig* [*a sales division of Pfizer*] *are abiding by reduction of samples* because the number of calls from all reports from the field since

> my return from Absecon, have been practically none. (Emphasis added) (CX 593B)

And, on June 17, 1954, he wrote:

> Within the last thirty days, complaints from the field regarding the Pfizer and Roerig operations have been practically nil. From all indications, it is presumed that these competitors *are adhering to the operation that was reported by Mr. Wendt* [Cyanamid's Director of Sales] at the Regional Manager's meeting. (Emphasis added) (CX 594A)

About one year later the same Cyanamid representative made the following comment with respect to the furnishing of free tetracycline to Michael Reese Hospital, Chicago, Illinois:

> Approximately *one year ago,* we were furnishing this same institution material for clinic use through Dr. Kagan, Chief of Pediatrics. *This procedure was stopped due to a report by Pfizer to Mr. Wendt.* (Emphasis added) (CX 595)

The record also shows that in March 1955, shortly before a fourteen month period of noncompetitive bidding to the Veterans Administration, a Cyanamid representative reported that Pfizer was undercutting Cyanamid and "everybody" on bid prices to certain CCS hospitals. He then stated in the report that "This should be checked into and *prices arranged* as we have done on the VA setup." (Emphasis added) (CX 558B)

Another Cyanamid representative stated on July 30, 1955:

> If Pfizer is trying to hold the price line, would it be helpful to collect some copies of bids showing the

low-cut bids by Pfizer's accounts so that Pearl River [Cyanamid] could show them to Pfizer officials? (CX 579B)

Both Cyanamid and Pfizer, however, were concerned over bulk sales by Bristol, since both believed that additional marketers of tetracycline could disrupt the stabilized price structure. Their views on this subject are clearly revealed by conversations between Pfizer's officials and Schwartz, president of Bristol; by Pfizer's announced intention to "stop" Bristol, after the latter began selling in bulk to Squibb and Upjohn; by statements of Cyanamid's officials before the Patent Office; and by Cyanamid's suit to stop Bristol shortly after Bristol began selling tetracycline in bulk in September, 1954. (See Findings 8, 11, 16 and 17).

All the firms were in touch with each other, from the settlement of the first interference, throughout the prosecution of the second interference, during Pfizer's patent infringement suit, continuing through the licensing arrangements and thereafter.

As early as May 1954, Bristol, which just recently had entered the market, was exchanging price lists with Upjohn, its customer and competitor; Bristol was assured that " . . . there will be no question as to your receiving the proper pricing information."

May 24, 1954

Mr. Owen Baughman
General Sales Department
The Upjohn Company
Kalamazoo, Michigan

I am in receipt of your very nice letter of May twentieth, and in reply I would like to suggest that the supplements and revisions to the catalog you have earmarked for Mr. W. A. Owen in Syracuse be changed to:

Manager, Sales Service Dept.
Bristol Laboratories, Inc.
Syracuse 1, New York.

By doing it this way, the material will be delivered to the proper person.

We are contemplating including a loose-leaf pricing schedule in the Therapeutic Manual, and at that time there will be no question as to your receiving the proper pricing information.

However, until that is done, I am enclosing our latest pricing schedule. This in turn is due for revision shortly, as it is currently full of stickers containing additional pricing information.

I believe that currently we have sufficient of your catalogs. Again, thank you for your very nice letter.

Very truly yours,

Bristol Laboratories, Inc.
Paul T. Rees
Sales Manager

(CX389)

Then in November, 1954, after the dissolution of the second interference—Upjohn, Bristol's customer sent Cyanamid its "domestic catalog".

November 29, 1954

A Domestic Catalog was mailed today to:

Lederle Laboratories Div.,
American Cyanamid Co.,

Att: Mr. Robert S. Andrews,
International Sales Education
30 Rockefeller Plaza
New York 20, N. Y.

Will you please add the above to your mailing list, to receive new and replacement pages as they are issued." (CX391)

Again in June of 1955, in the midst of Pfizer's struggle to oust Bristol, Squibb and Upjohn from any role in the tetracycline market, H. H. Kibbe, Manager of the Pfizer "Pricing Department" wrote to his counterpart at the Upjohn Company:

Under separate cover, we are sending you a copy of the new Pfizer Laboratories loose-leaf Price Schedule. When new products are added to our line, you will receive supplemental price pages in the form of "Pfizer Scripts", a new series of price and product information folders. These pages, when inserted in the proper sequence as indicated, will keep your price list up to date.

We would like you to mail a copy of your current catalog to the writer's attention and will appreciate your placing your name on our mailing list for new product and price change information.

Thank you for your prompt attention.

(CX392) H. H. Kibbe

The reply from Upjohn was as follows:

June 9, 1955

Thank you very much for sending us a copy of the new Pfizer Laboratories loose-leaf price schedule. We will also look forward to receiving the 'Pfizer Scripts' and will see that they are inserted promptly to keep your price list up to date. Information folders should be directed to my attention.

We have mailed you a copy of the Upjohn catalog, and your name has been placed on our mailing list

so that you will receive reprinted pages as they are prepared. (CX393)

Then on January 18, 1956, Bristol's Sales Service Department wrote to Upjohn as follows:

Thank you very much for your prompt attention and reply to my letter of January 13th. In regard to your mailing list concerning Bristol Laboratories, Inc., you may remove Mr. W. A. Owen's name from the list. Mr. Owen is no longer connected with the Sales Department. We will appreciate your listing

Bristol Laboratories, Inc.	Bristol Laboratories, Inc.
630 Fifth Avenue	Sales Service Department
New York, New York	P.O. Box 657
—and—	Syracuse, New York

for additional information which you may distribute in the future.

Two (2) Bristol Therapeutic Manuals will be sent to Mr. H. E. Shepard promptly and we have added Mr. Shepard's name to our mailing list.

Two (2) new pages for the Therapeutic Manual have been issued since June 1955. I have asked that these be mailed to your attention. (CX395)

In 1957, Mr. Kibbe of Pfizer, once more contacted Mr. Shepard of Upjohn to insure that both firms had an up to the minute knowledge of each others pricing practices.

Pfizer Laboratories

"July 24, 1957

Under separate cover we are sending you a complete new set of price pages for your Pfizer Laboratories loose-leaf catalog. Kindly remove all pages from your present cover and insert this refill.

> When new products are added to your line, you will receive announcements in the form of 'Pfizer Scripts', a new series of price and product information folders. These pages when inserted in the proper sequence will keep your copy of our price list up to date.
>
> "Thank you for your cooperation." (CX400)

The entry of Squibb and Upjohn into the tetracycline market created some problems, but not ones as serious as those anticipated by Cyanamid and Pfizer. Both of the newcomers were endeavoring to adhere to established prices, but the mere increase in the number of sellers increased the likelihood of price variations. For example, the record shows that Squibb and Upjohn were giving CCS prices to a hospital which Cyanamid had classified as NPA. A Cyanamid memorandum (CX 581) recommended that Squibb and Upjohn be contacted with reference to their classification of this hospital. The record also shows that even though all the respondents may have been aware of the mutual benefits to be derived by avoiding price competition, none of them could be sure that it could always depend on the others to adhere to the prevailing price without continued surveillance and conspiratorial action. This was particularly true in hospital and federal markets where large spot sales could be captured by small price reductions.

An agreement among the five respondents, Pfizer, Cyanamid, Bristol, Squibb and Upjohn, not to deviate from published prices was therefore necessary to insure uniformity of price quotations.

Shortly before the tetracycline patent infringement suit was settled, Cyanamid's Director of Sales wrote the following letter to Bristol's Director of Sales:

11/22/55

Dear Dick:

I am enclosing the most recent prices on all of our Achromycin (Cyanamid's trade mark for tetracycline) prices, together with what we call a Trade Class chart. This Trade Class chart is our standard procedure for classifying accounts for our Lederle Purchase Plan and our handling charge policy.

Our branches are instructed to follow this chart with great precision. Basically, except for the subject of our discussion Friday afternoon, there are no deviations. I might say that the branch offices do not report to the Sales Department but rather to the Treasurer's Office, so that the opportunity for special situations is non-existent.

Our Dominion price for 250 mg. has been and will continue to be $17.01. This price applies to the Department of Defense Production and the Department of Veterans Affairs. Our price to the Canadian Provincial Department is $25.50.

The name of the hospital survey group is Davee, Koehnlein & Keating at One North LaSalle Street, Chicago, Illinois.[80]

Sincerely,

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[80] This letter, found by a Commission attorney in Bristol's files, was in a mutilated condition with the identity of the sender removed therefrom. Bristol's explanation of the existence of the document and its condition prompts us to react to Bristol's explanation in a manner similar to Mr. Justice Jackson's reaction to the majority opinion in the second *Chenery* case: "I give up. Now I realize fully what Mark Twain meant when he said, 'The more you explain it, the more I don't understand it'." *S.E.C.* v. *Chenery Corp.*, 332 U.S. 194, 214 (1947).

Opinion of the Commission

We think it clear from the text of this letter (CX 328) that the writer was referring to *all* of Cyanamid's Achromycin prices in the first two paragraphs thereof, thus, both the prices in the United States and Canada. Furthermore, there was no evidence introduced to indicate that the policies referred to in the first two pararaphs were limited to Canada or that these policies were not equally applicable in the United States—for example, "that the branch offices do not report to the Sales Department but rather to the Treasurer's Office, so that the opportunity for special situations is non-existent." It was only in the third paragraph that the writer specified Canadian prices.

The most significant feature of this document is that it contains assurances to Bristol that Cyanamid would adhere to its published prices. Certainly Cyanamid would not give such assurances to Bristol without an understanding that it would not be undercut by Bristol. Clearly both firms must have agreed not to deviate from the published prices.

In the third paragraph the writer discusses Cyanamid's price for 250 mg. capsules to agencies of the Canadian government. The Dominion price was secret information, but Cyanamid not only furnished it to Bristol but again gave assurance that the price "will continue to be $17.01." It is also of some significance in this connection that Pfizer was also bidding $17.01 to the Canadian government.[81]

The conclusion is also inescapable that Cyanamid would not have given such secret information to Bristol unless it had received assurance that Bristol would not undercut this price.

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[81] The examiner erroneously found that Cyanamid and Pfizer were bidding at different prices since Pfizer had bid $16.67 and Cyanamid had bid $17.01. Cyanamid's bid of $17.01, however, less its usual 2% discount amounts to $17.01 less $.34 or $16.67.

Within a few weeks the infringement suit was settled, and Pfizer licensed Bristol, Squibb and Upjohn to sell under its patent. An awareness or recognition of an agreement on prices is reflected in various documents such as the following memoranda and letters written after settlement of the aforesaid infringement suit.

On December 16, 1955, the Squibb Manager of Marketing wrote:

> On Bid No. 635 for 100's of tetracycline 250 mg. Lederle's product was offered at $21.08 per 100. *In order to properly record this violation I must know whether this was a direct bid by Lederle, or whether the bid was made through a dealer.* (Emphasis added) (CX 220)

On April 5, 1956, the same official wrote:

> In checking back over your recent report on Tetracycline Bids to the King County Hospital, I notice that Joseph Hart and Northwest Medical quoting on the Pfizer product cut the price to $20.23 and $20.44 respectively. Bracken quoting on the Lederle product quoted $21.00.
>
> * * * * *
>
> You will notice that all three dealers quoted within the frame work of their 10% handling credit. *We can only assume that it was a decision made by the dealers and that there is no official approval of what they are doing.* Of course, our own bid must be strictly in accord with the schedule. (Emphasis added) (CX 222)

The following sales memorandum was prepared on May 11, 1957, by a Bristol official:

> On a bid that opened on 5-10-57 for the Ohio State University Hospital which called for a 10-100 Tetra-

cycline Phosphate Complex, both Bristol and Upjohn conformed to the state price whereas Squibb bid it at 22.04 net. I fully realize that 22.04 net is theoretically the same as 22.49 less 2%, and on this particular bid it amounts to the same thing. However, supposing the bid had called for 100-100 or 150-100 which they have been buying of the HCI Salt, then Squibb would have been awarded the bid because they would have been .02 or .03 less than our bid.

I am only calling this to your attention Charlie in order to stop whatever precedent may occur in the future. This is a very technical point, but as you know, .02 or .03 can make the difference whether you are awarded the bid or not.

The bid or Inquiry No. is 2791-D-61510, and was signed by Paul Wherry, one of the Squibb representatives.

I hope this does not happen in the future, *and if we can nip it in the bud I am sure that it will not be tried elsewhere.* (Emphasis added) (CX 843).

5. In addition to the evidence referred to above, there are also in the record other documents which establish beyond doubt that respondents did not compete pricewise and that they deliberately confined their rivalry in the tetracycline market to areas other than price. In view of this evidence, certain inferences drawn by the hearing examiner from a shift in market shares is without foundation. For example, he has drawn an inference from a shift in the shares of the retail market held by Cyanamid and Pfizer to Bristol, Squibb and Upjohn that there was price competition and that no price fixing conspiracy existed among the five firms. The record shows, however, and respondents have conceded, that the prices to retailers were uniform throughout the period relevant to this proceeding. Consequently, the shift in shares in the retail market could not have been caused

by price differences or price competition and the shift might have occurred whether or not these prices were fixed by agreement.

When Bristol, Squibb and Upjohn entered the tetracycline market, selling the same product at the same price as that charged by Cyanamid and Pfizer, some shift in market shares could reasonably be expected. While the "lead time" in tetracycline sales enjoyed by Cyanamid and Pfizer may have given these firms a significant initial advantage over Bristol, Squibb and Upjohn, no one, except the hearing examiner, has seriously suggested that it constituted an absolute barrier to sales by the new entrants in the market. Under the circumstances, changes in market shares were bound to occur. Moreover, the record shows that respondents did compete in promoting their respective brands of tetracycline in many ways short of actual price competition. The examiner, however, has completely ignored the existence of other forms of competition in drawing the inference that the shift in market shares was caused by price competition. At best the evidence of a shift in market shares is but one "neutral" factor.

The importance of other competitive methods is best demonstrated by respondents' own writings. To illustrate, the following statement from a report by Bristol Laboratories to Bristol-Myers on April 25, 1955, emphasizes the role of the "detail man":

> The chief market for our penicillin has always been the hospital. This was true because penicillin sales were largely sales of injectable items. Furthermore, purchases were generally quantity purchases. The price situation was such that on these quantity purchases, the company's willingness to meet price cuts of competitors rather than the salesman's ability was the final determining point in our getting or losing a sale.
>
> Tetracycline sales, on the other hand, are overwhelmingly prescription sales. Our price is no lower than

> the prices of competition. Sales result when the detail man convinces a physician that our product and service offers advantages over that of someone else. The salesman has thus become the key factor in the case of injectable penicillin. (CX 370B).

The lack of emphasis on price competition is shown by the following memorandum prepared by Upjohn shortly after it entered the tetracycline market:

> It has been brought to our attention that you are inferring or directly stating to the physician that the Upjohn Company is going to reduce, lower or bring the price down on Panmycin. This, I am sure, is the farthest point in our minds . . .
>
> I urge you to refrain from implying or directly stating that it is our intention to reduce the price and that we make no mention of our doing so in our details.
>
> We should have no reason to assume that the price could or would be reduced in the near future. With the price and market already established, I feel we need not use the price discussion as the cardinal point in our detail. . . . (CX 390),

and the following letter concerning CCS prices prepared by a Squibb official in 1957:

> Concerning the bid which will be opened on the 18th proposal #125478 I am wondering about the price of .67 net you quoted on 24 vials of Steclin IM 100 mg. Regardless of the amount involved we have never been able to drop the mills in connection with Tetracycline IM. In other words, we quote .6713 net and not .67.
>
> This is a matter of considerable concern because our price would be lower than that of our major competitors were we to drop the mills.
>
> Will you please advise me concerning your authority for this .67 price? (CX 244).

XIV

Conclusions as to the Price Fixing Charge to Cyanamid, Bristol, Squibb, Upjohn and Pfizer

We have examined with care each document and the entire transcript of record. Being aware of the seriousness of a price fixing charge, we have not blithely assumed that casual comment and chance remarks amount to conspiratorial contact. To the contrary, we have examined all conflicting evidence and the reasonable inferences to be drawn therefrom. We can only come to one conclusion—that respondents, Cynamid, Pfizer, Bristol, Squibb and Upjohn conspired to fix and maintain prices.

There is of course little evidence of any *express* agreement to do what the law forbids but no such "evidence is required, nor is the Commission required to accept the denials of those charged with the conspiracy, merely because there is no direct evidence to establish it . . ." *Bond Crown & Cork* v. *Federal Trade Commission,* 176 F. 2d 974, 979 (4th Cir., 1949), and as was emphasized recently by the Supreme Court: ". . . judicial inquiry is not to stop with a search of the record for evidence of purely contractual arrangements . . . Whether the conspiracy was achieved by tacit agreement or by acquiescence . . . coupled with assistance in effectuating its purpose is immaterial".[82]

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[82] *United States* v. *The Singer Manufacturing Company,* 31 U.S. L. Week 4074 at p. 4680, quoting and citing with approval from *United States* v. *Bausch & Lomb Optical Co.,* 321 U.S. 707, at 723 (1944).

Moreover, this Commission itself has been sustained as a fact finder when it relied upon one single hearsay document to prove a conspiracy. As the court composed of Judges L. Hand, Frank and Swan stated in that case, "[i]t is true that . . . [the] memorandum is hearsay; but it is persuasive hearsay and the Commission is not bound to follow the strict rules of evidence which prevail in courts of law. (*John Bene & Sons* v. *Fed. Trade Com.,* 299 Fed. 468 (CCA 2).)" See *Phelps Dodge Refining Corporation* v. *F. T. C.,* 139 F. 2d 393, 397 (1943).

Admittedly, we do not have a record with the "True Confessions" of each respondent of its role in the price conspiracy. We have a record of both direct and circumstantial evidence interspersed with documents, letters and memoranda exchanged between the key sales and pricing department managers of the various respondents, and intracorporate documents referring to prior intercorporate contacts on prices, price uniformity and "violations" of price uniformity. Cf. *Schine Theaters* v. *United States*, 334 U.S. 110 at 117 (1948).

". . . neither knowledge of the conspiracy alleged nor participation therein need be proved by *direct* evidence, even in criminal prosecutions where the rule of proof is more strict than in civil conspiracy cases." *Flint Kote Co.* v. *Lysford*, 246 F. 2d 368 (9th Cir., 1957), cert. denied, 355 U.S. 835. (Emphasis Added) And in *Paoli* v. *U.S.*, 352 U.S. 232 (1957) the Supreme Court declared:

> "Participation in a criminal conspiracy may be shown by circumstantial as well as direct evidence."

Speaking in more colorful terms the Ninth Circuit said in *C-O Two Fire Equipment Co.* v. *United States*, 197 F. 2d 489, 494 (9th Cir., 1952):

> "A conviction resting solely upon circumstantial evidence is not an innovation. It is we think well established that the proof and evidence in an anti-trust conspiracy case is in most cases circumstantial. Proof of a formal agreement is unnecessary, and were the law otherwise such conspiracies would flourish; profit rather than punishment would be the reward."

Nor can we accept respondents' contention that the conspiracy must be completely proven by direct evidence. Even in criminal cases "circumstantial evidence such as [does not] exclude every reasonable hypothesis other than

that of guilt", may be the basis of a finding of guilt. *Holland* v. *United States*, 348 U.S. 121, 139 (1954).

In addition we have been alert to "the dangers of transference of guilt from one to another across the line separating conspiracies", cf. *Kotteakos* v. *U.S.*, 328 U.S. 750, 776 (1946). Moreover, in contrast to *Kotteakos, supra*, we conclude that there is but one conspiracy and in this one conspiracy" . . . the guilt or innocence of each defendant [has been] determined by [us] separately". See *Blumenthal* v. *United States*, 332 U.S. 535, 560 (1947). And once the conspiracy is established "a relatively small amount of evidence connecting a particular defendant will suffice . . ." *Morton Salt Company* v. *United States*, 235 F. 2d 573, 580 (10th Cir., 1956). Finally, we wish to make it clear that this is not a case of "conscious parallelism" Cf. *Theatre Enterprises, Inc.* v. *Paramount Film Distributing Corp.*, 346 U.S. 537 (1954). Here we find an active conspiracy in which all the respondents shared in the ill gotten fruits originally secured by Pfizer at the Patent Office.

In conclusion, we find that all five of the respondents, Cyanamid, Bristol, Squibb, Upjohn and Pfizer, conspired to fix and stabilize prices in the prescription NPA and CCS markets. That a conspiracy of this nature is a violation of Section 5 is beyond cavil: See *Federal Trade Commission* v. *Motion Picture Advertising Service Co.*, 334 U.S. 392, 395 (1953).

XV

Discussion of Remedies

We turn now to the problem of an adequate remedy. By reason of the conspiracy found herein, respondents have restrained price competition among themselves. Accordingly, the final order contained herein requires each respondent to cancel existing price lists and independently to determine new prices based on its own manufacturing

and overhead costs and desired margin of profit.

As a necessary prelude to free and effective competition in the tetracycline market, one possible remedy is an order against Pfizer and Cyanamid enjoining them from refusing to give licenses under their tetracycline and Aureomycin patents. Courts have long deemed a compulsory license decree an appropriate remedy to antitrust misuse of patents. *Hartford Empire Co.* v. *United States,* 323 U.S. 386 (1945); *United States* v. *National Lead Co.,* 332 U.S. 319 (1947); *United States* v. *United States Gypsum Co.,* 340 U.S. 76 (1950). Although such decrees usually include a provision allowing the patentee to collect reasonable royalties, it is by no means settled that compulsory royalty-free licensing (or an injunction against enforcement of the patent) is beyond a court's discretion in all cases. In *Hartford Empire Co.* v. *United States, supra,* the Court refused to grant the government's request for a royalty-free decree and indicated that such remedy was not within a court's power unless so provided by Congress. But in *United States* v. *National Lead Co., supra,* at 338, the Court expressly left open this question (and the question of constitutionality of such a decree) for consideration in future cases.

The matter has not yet been authoritatively settled, but some courts have proceeded on the assumption that they have such authority. The District Court in *United States* v. *General Electric Co.,* 115 F. Supp. 835 (D. N.J., 1953) found the defendants had restrained trade in the sale of electric lamps. The court ordered dedication of all existing patents on the lamps with this explanation: "To compel the completely free use of these patents is not to impose upon General Electric and other defendants penalties for misuse of patents and violation of the antitrust laws, but rather to check the intrusion of advantages thereby gained into the mechanics of competition in the lamp industry." The court decided that the defendants should not be given the advantage of reasonable royalties, since many

patents were involved and requiring the smaller operators "to shoulder royalties . . . could prove to be the very factor that would push them out of the competitive circle of the market." *Id.* at 844. See also *United States* v. *American Can Company,* 1950-1951 Trade Cases, Par. 62,679 (N.D., Cal., 1950) and *United States* v. *Radio Corporation of America,* 1959 Trade Cases, Par. 69,459 (E.D. Pa., 1959) (Consent Decree).

It has been suggested that in compulsory license decrees the defendant be allowed to impose royalties when and if it can convince the court that the effect of its illegal activity has been fully dissipated. See *Report of the Attorney General's National Committee to Study the Antitrust Laws,* 256 (1955). Also, we think the decisions make it clear that compulsory disclosures of know-how and technical assistance are proper adjuncts to a compulsory licensing mandate when the circumstances demand it. See, *e.g. United States* v. *National Lead Co., supra.*

This Commission "is clothed with wide discretion in determining the type of order that is necessary to bring an end to the unfair practices found to exist". *Federal Trade Commission* v. *National Lead Co.,* 352 U.S. 419, 428 (1957). We think that under the applicable decisions and considering the nature of Pfizer's and Cyanamid's misconduct before the Patent Office, this Commission has adequate authority to require a royalty-free license *"if it is necessary to pry open to competition a market that has been closed by* [*respondents'*] *illegal restraints."* (*International Salt Co., Inc.* v. *United States,* 332 U.S. 392, 401 (1947).)

We feel it our duty to consider carefully the alternative forms of remedy available to suppress the effects of these respondents' actions. For this reason we are not now issuing a final order on the future use of tetracycline and Aureomycin patents but desire complaint counsel and respondents to submit their own respective proposed orders in conformity with our decision together with reasons in

support thereof. A separate order accompanies this decision setting forth the questions to be discussed.

Commissioner Anderson concurs in part and dissents in part. Commissioner Elman's position in this case is set forth in a separate opinion.

August 8, 1963

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Paul Rand Dixon, Chairman
Sigurd Anderson
Philip Elman
Everette MacIntyre
A. Leon Higginbotham, Jr.

In the Matter of AMERICAN CYANAMID COMPANY, et al.	DOCKET NO. 7211

By Commissioner Anderson, concurring in part and dissenting in part:

I concur in the result reached by the Commission in this proceeding. However, I feel constrained to say that, in my opinion, it is only by the narrowest margin that the evidence supports the allegation as to price fixing by Squibb and Upjohn.

It is also my view that Paragraph 1 of the order to cease and desist is far too broad. In the first place, we have found that respondents have "engaged in unfair methods of competition by conspiring to fix and maintain the selling price of tetracycline" but our order relates to all antibiotics, both broad and narrow spectrum. Secondly, the order, by the inclusion of the words "knowingly common course of action," would prohibit respondents from engaging in pricing practices falling far short of those alleged in the complaint and found to be unlawful. For the first time, to my knowledge, it appears that we are prohibiting consciously parallel behavior, even though such behavior does not stem from agreement, tacit or express, but is merely the independent decision of one firm to follow the price leadership of another.

August 8, 1963

UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Paul Rand Dixon, Chairman
Sigurd Anderson
Philip Elman
Everette MacIntyre
A. Leon Higginbotham, Jr.

In the Matter of	DOCKET No.
AMERICAN CYANAMID COMPANY, a corporation, et al.	7211

Commissioner Elman:

Mr. Justice White, concurring recently in a case not wholly dissimilar to the instant case, said: "[C]learly collusion among applicants to prevent prior art from coming to or being drawn to the [Patent] Office's attention is an inequitable imposition on the Office and on the public. In my view, such collusion to secure a monopoly grant runs afoul of the Sherman Act's prohibitions against conspiracies in restraint of trade. . . ." *United States* v. *Singer Mfg. Co.*, 31 U.S. L. Wk. 4674, 4682 (citations omitted). Here we have not collusion, but deliberate material misrepresentations to prevent prior art from coming to or being drawn to the Patent Office's attention, as the keystone of an effort to secure a monopoly grant; not a conspiracy in violation of Section 1 of the Sherman Act, but an attempt to monopolize a substantial market in violation of Section 2 of that Act and Section 5 of the Federal Trade Commission Act.

As the Commission's opinion and findings convincingly demonstrate, respondent Pfizer deliberately misrepresented to the patent examiner the state of the prior art bearing

upon the patentability of tetracycline, and its misrepresentations were material to its obtaining a patent on tetracycline. If Pfizer's conduct before the Patent Office amounted to fraud, the patent procured thereby would be cancellable in an appropriate proceeding. *United States* v. *American Bell Telephone Co.*, 128 U.S. 315, 370. (This would not mean, of course, that tetracycline was unpatentable, but only that Pfizer's patent on tetracycline was invalid.) But the Commission need not, and, as I understand its opinion, does not, determine in this Section 5 proceeding whether Pfizer's patent is invalid for all purposes and under all conditions.

The evidence of record demonstrates beyond cavil that Pfizer procured the patent for the purpose of monopolizing the manufacture of tetracycline, or, what amounts to the same thing, of permitting the manufacture of tetracycline by others only on terms acceptable to Pfizer. The patent was obtained in order to prevent competition in the manufacture and distribution of tetracycline. Pfizer well knew that if tetracycline, like penicillin, could be freely manufactured and sold by others on a competitive basis, its price would fall steeply just as the price of penicillin had fallen in the recent past. By procuring a patent on tetracycline, and thereafter licensing its manufacture selectively, Pfizer created, and succeeded in maintaining, a non-competitive price structure in the tetracycline industry—and, as a result, the price of tetracycline has remained at the uniform high level established when it was first produced.

In my opinion, Pfizer's conduct, viewed in its entirety in the setting of the tetracycline market, violated Section 2 of the Sherman Act and therefore Section 5 of the Federal Trade Commission Act.

To be sure, one who, in attempting to achieve monopoly power in an industry through obtaining and then exploiting a patent, does no more than prosecute successfully a patent application in the manner prescribed by law, does not violate the antitrust laws. Such an "attempt to monopolize",

unaccompanied by collusion or fraud, is privileged by the patent laws. But Pfizer cannot find shelter in the patent laws for its attempt to monopolize the tetracycline market, because in prosecuting its application for a patent, Pfizer breached the legal duty it owed the Patent Office of full and fair disclosure of material facts. The short of this case is that Pfizer's attempt to monopolize the manufacture of tetracycline could not succeed unless a patent were issued to it; in attempting to secure the patent, Pfizer deliberately made material misrepresentations concerning the prior art; its conduct, being "an inequitable imposition on the Office and on the public," could not be legitimized by anything in the patent laws, and consequently stands forth as a plain violation of Sections 2 and 5. And this is so whether or not the patent itself be deemed invalid by reason of Pfizer's wrongful conduct in acquiring it. The point here is that such conduct makes unavailable to Pfizer any justification or defense, to the charge of unlawful attempted monopolization, predicated on the patent laws.

Furthermore, since the "unfair methods of competition" proscribed by Section 5 are not confined to those made unlawful by the Sherman Act, it is not necessary that a violation of Section 2 be found. See *Federal Trade Commission* v. *Motion Picture Advertising Service Co.*, 344 U.S. 392. Pfizer's conduct comes sufficiently within the general range of the evils which Section 2 was designed to remedy as to constitute an unfair method of competition within the meaning of Section 5.*

My conclusion that Pfizer has violated Section 5 does not, of course, rest upon the premise that the prosecution

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* Respondent Cyanamid's misrepresentations to the patent examiner, which were designed to enable Pfizer to obtain its patent for the purpose of fostering an anticompetitive market structure from which Cyanamid along with Pfizer would reap benefits, seem to me also to violate Section 5 and justify an order respecting the Cyanamid patent on Aureomycin insofar as Aureomycin is the raw material from which tetracycline is produced by the deschlorination process.

of a patent application before the Patent Office in circumstances giving rise to an inference of "unclean hands", "inequitableness", "bad faith", and the like constitutes, without more, an unfair method of competition in violation of Section 5; nor do I view the Commission's decision as based on so sweeping a ground. Not every patent is commercially valuable or confers on the patentee the power to monopolize or to restrain competition in a substantial market. Implicit in the disposition of this case, as I see it, is a recognition that tetracycline is a unique and valuable product, commercially as well as therapeutically; and its manufacture and sale compose a substantial market. An attempt to monopolize such a market is a violation of Section 5, and no less so because the monopolistic scheme embraces the securing of a patent by fraud or misrepresentation. Pfizer's conduct, in its totality, constituted such an iliegal attempted monopolization. But our concern, it must be emphasized, is not with unfairness, as such, in the prosecution of patent applications before the Patent Office. This Commission was established to preserve and protect *competition*, and frauds or misrepresentations occurring in proceedings before the Patent Office become our concern only to the extent that they affect competition.

Pfizer's violation of Section 5 justifies an order limiting Pfizer's free enjoyment of its patent in such fashion as to establish and maintain in the tetracycline industry conditions favorable to competition. Certainly the order should compel Pfizer, at the very least, to license its patent on equitable terms to all firms that wish to enter the tetracycline market. If effective relief along these lines should be directed, the serious questions involved in the price-fixing part of this case will become almost academic. As the Commission in its opinion seems to recognize, the basic factor making for price uniformity in the tetracycline industry is not any conspiracy or agreement among respondents, but the economic structure of the industry, which is the consequence of Pfizer's patent. As a result of Pfizer's suc-

cess in obtaining a patent, and its selective licensing thereunder, the industry, both in its manufacturing and marketing aspects, contains very few firms; in a word, it is oligopolistic. In such an industry, economists tell us, each firm may decide individually not to engage in substantial price competition, even when demand for its products slackens, because each firm realizes that its price cut will be quickly matched by its competitors, resulting in diminished profits for all. The structure of such an industry, then, will compel or invite non-competitive pricing independently of the existence of overt agreement among competitors. There may or may not be an agreement among respondents, unlawful under Section 1 of the Sherman Act, to pursue an industry-wide policy of non-competition in price; but plainly it is the market structure built upon Pfizer's wrongfully procured patent, and not any actual agreement, that has closed the door to competition, and will tend to keep the door closed even if the agreement is enjoined.

If the Commission, by an order designed to overcome Pfizer's attempt to monopolize, opens the industry to competition, new firms are bound to enter and in that event the industry's oligopolistic structure will rapidly crumble. When this happens, the salutary purposes of this proceeding will be accomplished, and the necessity or appropriateness of relief directed against any price-fixing agreement among the present firms in the industry, *i.e.*, the respondents herein, will disappear. The alleged price-fixing agreement here is tailored to the existing structure of the industry, and only the existing members of the industry are alleged to be parties to it; once that structure changes by order of the Commission, the existing agreement will be deprived of its efficacy. Accordingly, in my view of the case it is unnecessary to reach, and I express no opinion upon, the Commission's finding of a price-fixing or price-stabilizing conspiracy, and its proposed order based upon such finding.

August 8, 1963

First Opinion of Court of Appeals, 363 F.2d 757

Nos. 15805, 15797, 15801, 15806, 15788

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

AMERICAN CYANAMID COMPANY,
Petitioner,
v.
FEDERAL TRADE COMMISSION,
Respondent.

BRISTOL-MYERS COMPANY and
BRISTOL LABORATORIES INC.,
Petitioners,
v.
FEDERAL TRADE COMMISSION,
Respondent.

CHAS. PFIZER & CO., INC.,
Petitioner,
v.
FEDERAL TRADE COMMISSION,
Respondent.

OLIN MATHIESON CHEMICAL
CORPORATION,
Petitioner,
v.
FEDERAL TRADE COMMISSION,
Respondent.

THE UPJOHN COMPANY,
Petitioner,
v.
FEDERAL TRADE COMMISSION,
Respondent.

ON PETITIONS to Review an Order of the Federal Trade Commission.

Decided June 16, 1966.

First Opinion of Court of Appeals, 363 F.2d 757

Before O'Sullivan, Phillips and Celebrezze, Circuit Judges.

Phillips, Circuit Judge. This case presents for review an order of the Federal Trade Commission holding that petitioners violated Section 5 of the Federal Trade Commission Act.[1] in connection with the production and sale of tetracycline, which is described as "currently the best selling wonder drug in the United States."[2]

The Antibiotics Industry

Tetracycline, a broad-spectrum antibiotic, is sold and distributed under various trade names by all five petitioners: Chas. Pfizer & Co., Inc. ("Pfizer"), American Cyanamid Company ("Cyanamid"), Bristol-Myers Company and Bristol Laboratories ("Bristol"), Olin Mathieson Chemical Corporation through its E. R. Squibb & Sons Division ("Squibb") and the Upjohn Company ("Upjohn"). Pfizer owns the patent on tetracycline and produces it in addition to selling and distributing.

Under licenses granted by Pfizer, Cyanamid and Bristol also produce this anitbiotic as well as selling and distributing it. Squibb and Upjohn sell and distribute by authority of licenses granted by Pfizer.

Also involved are two older antibiotics: (1) chlortetracycline, which is produced and sold by Cyanamid, owner of its patents, as aureomycin; and (2) oxtetracycline,

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[1] 15 U.S.C. § 45(a)(1): "Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful."

15 U.S.C. § 45(a)(6): "The Commission is empowered and directed to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce."

[2] N.Y. Times, March 29, 1964, § 1, p. 1, col. 1. See discussion of this case in 77 Harv. L. Rev. 1505.

which is produced and sold by Pfizer, owner of its patent, as terramycin.

Antibiotics are chemical substances produced by certain microorganisms. They have the capacity to counteract and cure a broad variety of diseases. At the end of World War II, penicillin was the principal antibiotic. It was a "narrow-spectrum" drug with more limited effectiveness than the later "broad-spectrum" antibiotics. Penicillin was not patented. Its production and sale proved to be fiercely competitive and profits were marginal.

The antibiotics involved in this case were described by the Commission as follows:

> "The earlier antibiotics such as penicillin and streptomycin are known as narrow spectrum antibiotics because they are normally effective against either gram-positive or gram-negative bacteria but not both. The antibiotics with which this case is concerned are known, beginning with the discovery of Aureomycin, as broad spectrum antibiotics because they are effective against a far wider range of bacteria, including both gram-positive and gram-negative bacteria. Because of their wide-range of efficacy against practically all infectious diseases, the broad spectrum antibiotics have become known popularly as 'wonder drugs'. Their use results in a marked decrease in the cost of treating those diseases, and they presently are prescribed in substantially all instances in which they are effective. Antibiotics are also employed to prevent infection or disease as, for example, prior to surgery, and to prevent recurrences of infection and disease. Antibiotics are therefore of vital and unique importance to the health and welfare of the general public.

"Antibiotics, including tetracycline, Aureomycin and Terramycin, as all ethical drugs, are products which can be obtained by the ultimate consumer or patient only under the authority of a doctor's prescription. Each is customarily prescribed by the physician under the respective brand name of the manufacturer, rather than its generic or chemical name. It is the physician's prescription which determines the amount and brand of drug which the pharmacist will sell. Consequently, respondents direct a major portion of their sales and promotional efforts at physicians, emphasizing their respective trade names. By law and custom, pharmacists are prohibited from substituting one brand of an ethical drug for another without permission of the physician."

Proceedings before Patent Office

When Cyanamid obtained a patent on aureomycin in 1949, the molecular structure of that drug was not known. The patent application described it in terms of certain secondary chemical properties. In 1952 the molecular structure was discovered, and a Pfizer scientist speculated that an antibiotic of at least equal strength could be produced by altering only slightly the structure of aureomycin. The result was a vastly improved antibiotic, tetracycline, which first was produced by Pfizer scientists in 1952.

Within six months of the discovery of tetracycline, both Pfizer and Cyanamid filed applications for patents.[3] The Patent Office declared an interference, which was settled as a result of a private cross-licensing agreement between Pfizer and Cyanamid to the effect that the party found to

[3] Pfizer's application is described in the record as the "Conover application" and Cyanamid's as the "Boothe-Morton application."

have priority would license the other. Thereafter Cyanamid conceded priority to Pfizer and withdrew its application.

Bristol then filed a patent application. A second interference was declared. The patent examiner filed an opinion which concluded that tetracycline was unpatentable. Pfizer thereupon submitted affidavits to the effect that tetracycline could not be recovered from broths representative of those described in the Cyanamid patent application on aureomycin. Shortly afterwards a product patent was issued to Pfizer.

The proceedings before the Commission primarily were concerned with the events leading up to the issuance of the tetracycline patent to Pfizer, which are described in some detail later in this opinion, the subsequent conduct of Pfizer and Cyanamid in exploiting the patent and the conduct by the five petitioners which the Commission found to constitute a conspiracy to fix the price of this drug.

The Complaint

The Commission's complaint, filed July 28, 1958, charged that Pfizer made false, misleading and incorrect statements to, and withheld material information from, the Patent Office for the purpose and with the effect of inducing the issuance of a patent on tetracycline; and that Cyanamid and Bristol withheld from the Patent Office material information in the course of the prosecution of the patent applications, as a result of which Pfizer was aided in obtaining its tetracycline patent.

It was further charged that, while both of their patent applications were pending, Pfizer and Cyanamid agreed that they would settle privately between themselves the question of which had priority on the invention of tetracycline, after which they would cooperate in securing the

awarding of a patent to the winner; that the owner of the patent then would license the unsuccessful party; and that the two would exchange information concerning the production of this drug.

The complaint avers that, pursuant to the terms of this prior agreement, Pfizer issued a license to Cyanamid to manufacture and sell the newly patented antibiotic. Cyanamid agreed to license Pfizer to use the process covered by the aureomycin patents in the production of tetracycline,[4] to furnish cultures and procedures for this purpose and to provide to Pfizer a quantity of bulk tetracycline so as to cut down the lead time that Cyanamid then had in the commercial marketing of the drug.

The complaint further charges that in March 1956, as a part of a settlement of an infringement suit brought by Pfizer, the latter also granted a license to Bristol to manufacture and sell tetracycline and, at the same time, licensed Squibb and Upjohn to sell this drug. It is further averred that all five petitioners fixed and maintained arbitrary and rigid prices through conspiracy and combination; and that petitioners have violated Section 5 of the Federal Trade Commission Act in that the activities of Pfizer before the patent office had and continue to have the effect of hindering, foreclosing, and eliminating competition in the sale of antibiotics and had and continue to have the dangerous tendency of creating a monopoly in Pfizer; and that all five petitioners, including Pfizer, through conspiracy and combination, have restrained, foreclosed and eliminated competition in the sale of antibiotics.

It is further charged that the antibiotics industry is one of dynamic growth, with sales exceeding $330 million per year, that tetracycline enjoys the largest sale by dollar

[4] This was first license ever granted by Cyanamid under its aureomycin patents.

volume, aggregating more than $100 million in 1957; and that petitioners account for all of these sales.

Proceedings Before Commission

The hearing examiner issued his initial decision, finding in favor of the petitioner drug companies on all issues, and dismissed the complaint.[5] On appeal, the Commission reversed, finding that the hearing examiner had misconstrued the actions of the patent examiner and the information which he deemed relevant to the application. The Commission found that Pfizer made deliberately false and misleading statements to, and withheld material information from, the Patent Office in securing its tetracycline patent; that this conduct amounted to "unclean hands," "inequitableness" and "bad faith" vis-a-vis the Patent Office; that Pfizer asserted monopoly rights under its patent in order to prevent competition in the tetracycline market; and that the effects of Pfizer's acts and conduct before the Patent Office have been to restrain competition, to foreclose access to substantial markets to competitors and potential competitors, and to create a monopoly in the manufacture and sale of tetracycline in violation of Section 5 of the Federal Trade Commission Act.

The Commission further found that Cyanamid made erroneous representations to the Patent Office concerning matters bearing upon the patentability of tetracycline; and that although Cyanamid soon discovered that these representations were inaccurate, it did not disclose this fact to the Patent Office until after the tetracycline patent had been granted to Pfizer, thereby aiding the latter in its efforts to obtain a patent. The Commission ruled that this suppression of material information, combined with the cross-licensing agreement between Pfizer and Cyanamid and the

[5] Summarized in Trade Reg. Rep. ¶ 15537 at pp. 20403-06 (1961).

acceptance by the latter of a license from the former to produce and sell tetracycline, constituted an illegal attempt to share a monopoly with Pfizer and amounted to a combination in restraint of trade. Similar charges against Bristol, Squibb and Upjohn were dismissed by the Commission, although these latter three companies were found guilty of price-fixing.

On the issue of price-fixing, the Commission decided that the record as a whole sustains the conclusion that the five petitioners fixed and maintained the price of tetracycline in substantial markets through conspiracy and combination.[6]

In August 1963 the Commission released the first two paragraphs of its final order, dealing only with the price-fixing aspects of this case. All five petitioners were ordered to cease and desist from (A) raising, fixing, stabilizing or maintaining prices or terms or conditions of sale; (B) discussing, conferring on or exchanging information for the purpose and with the effect of price-fixing; and (C) submitting collusive or rigged bids to purchasers or potential purchasers. All petitioners were directed to review prevailing prices for antibiotics; to determine new prices based on each petitioner's own manufacturing and overhead costs, the margin of profit individually desired, and other lawful considerations; and to cancel existing price lists.

On the issues relating to the tetracycline and aureomycin patents, the parties were directed to submit proposed forms of order with accompanying memoranda.

Thereafter, under date of December 17, 1963, the Commission entered its final order with an accompanying opinion. (See footnote 6). In addition to the provisions relative to the price-fixing aspects of the case, this order directs Pfizer to license its tetracycline patent to any

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[6] Trade Reg. Rep. ¶ 16527, pp. 21,389-21,445 (August 8, 1963); and ¶ 16699, pp. 21600-21606 (December 17, 1963).

domestic applicant on a two and one-half percent royalty basis and to provide the licensees with certain technical information. Under identical terms Cyanamid is directed to license its two aureomycin patents.

Motions to Disqualify Commission Chairman

The initial decision of the hearing examiner was announced October 31, 1961. (See footnote 5.) After notice of appeal to the Commission from this decision, all five petitioners filed motions on December 13, 1961, to disqualify Chairman Paul Rand Dixon from participating in the proceeding. These motions were filed pursuant to § 7(a) of the Administrative Procedure Act, 5 U.S.C. § 1006(a), and were based upon the contention that Chairman Dixon, in his former capacity as Chief Counsel and Staff Director of the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary of the United States Senate, played an "active role" in an investigation by that Subcommittee of many of the same facts and issues and of the same parties as are involved in this proceeding, and participated in the preparation of the report of the Subcommittee on the same facts, issues and parties. These motions to disqualify Chairman Dixon were made or renewed on three separate occasions prior to the Commission's final decision. The motions were denied.

Before this court petitioners take the position that the decision and order of the Commission are void because of the participation of Chairman Dixon therein. Before proceeding to other issues, it is necessary to pass upon this question.

The Issue of the Disqualification of the Commission's Chairman

The question of when a judicial officer is disqualified to sit in judgment in a particular case is one of the most difficult and delicate problems in judicial administration.

The basic rule was stated by the Supreme Court in *In re Murchison*, 349 U.S. 133, 136:

> "A fair trial in a fair tribunal is a basic requirement of due process. Fairness of course requires an absence of actual bias in the trial of cases. But our system of law has always endeavored to prevent even the probability of unfairness. To this end no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome. That interest cannot be defined with precision. Circumstances and relationships must be considered. This Court has said, however, that 'every procedure which would offer a possible temptation to the average man as a judge . . . not to hold the balance nice, clear and true between the State and the accused, denies the latter due process of law. *Tumey* v. *Ohio*, 273 U.S. 510, 532. Such a stringent rule may sometimes bar trial by judges who have no actual bias and who would do their very best to weigh the scales of justice equally between contending parties. But to perform its high function in the best way 'justice must satisfy the appearance of justice.' *Offutt* v. *United States*, 348 U.S. 11, 14."

This rule aplies to the Federal Trade Commission and other such administrative tribunals under the express terms of Section 7(a) of the Administrative Procedure Act of 1946.[7]

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[7] 5 U.S.C. § 1006(a):

"The functions of all presiding officers and of officers participating in decisions in conformity with section 1007 of this title shall be conducted in an impartial manner. Any such officer may at any time withdraw if he deems himself disqualified; and, upon the filing in good faith of a timely and sufficient affidavit of personal bias or disqualification of any such officer, the agency shall determine the matter as a part of the record and decision in the case."

Although the rule is clear, its application in particular cases presents practical difficulties.[8]

In approaching this problem in the present case we recognize that judicial officers "do not stand aloof on these chill and distant heights; and we shall not help the cause of truth by acting and speaking as if they do." Cardozo, *The Nature of the Judicial Process,* 168 (1921). It has been held that it was not necessarily "a violation of procedural due process for a judge to sit in a case after he had expressed an opinion as to whether certain types of conduct were prohibited by law." *Federal Trade Commission* v. *Cement Institute,* 333 U.S. 683, 702-3. A judicial officer is not disqualified because he "may have an underlying philosophy in approaching a specific case." *United States* v. *Morgan,* 313 U.S. 409, 421. A "strong conviction" or a "crystallized point of view" on questions of law and policy are not grounds for disqualification. 2 Davis, Administrative Law, § 12.01. "Federal Trade Commissioners, like other adjudicators, are entitled to hold and express views on the laws they are charged with enforcing and applying. . . . We do not equate impartiality with utter indifference. . . . We do not expect a Trade Commissioner to be neutral on antimonopoly policies." *Texaco Inc.* v. *Federal Trade Commission,* 336 F.2d 754, 764 (C.A. D.C.) (dissenting opinion of Judge Washington), vacated and remanded on another ground, 381 U.S. 739.

All of the motions to disqualify Chairman Dixon were supported by affidavits filed with the Commission. In an

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[8] See e.g. *Federal Trade Commission* v. *Cement Institute,* 333 U.S. 683, 700-3; Dixon, *"Disqualification" of Regulatory Agency Members: The New Challenge to the Administrative Process,* 25 Fed. B. J. 273 (Summer 1965); *Prejudice and the Administrative Process,* 59 Nw. U. L.Rev. 216, 231 (1964); *Disqualification of Administrative Officials for Bias,* 13 Vand. L.Rev. 713, 727 (1960).

effort to avoid lengthening this opinion, we are attaching as appendices the following documents:

Appendix A. Pfizer's affidavit in support of motion to disqualify Chairman Dixon. (Similar affidavits were filed by Cyanamid, Bristol, Squibb and Upjohn.)

Appendix B. Copy of a letter written by Senator Estes Kefauver to the Chairman of the Federal Trade Commission dated July 19, 1960.[9]

Appendix C. Copy of Commission's interlocutory order denying motions to disqualify Chairman Dixon. (59 Federal Trade Commission Decisions, 1488.)

Appendix D. Memorandum of Chairman Dixon in regard to motions that he be disqualified. (60 Federal Trade Commission Decisions, 1881.)

Appendix E. Excerpts from hearings before the subcommittee on antitrust and monopoly of the Committee on the Judiciary, United States Senate, on Administered Prices in the Drug Industry, 86th Congress, 1st and 2nd Sessions, Vol. 24 (1959-1960), in which Mr. Dixon participated as Chief Counsel and Staff Director.

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[9] The affidavit of Bristol's counsel contains the following charge with respect to this letter:

"On July 19, 1960 a letter was sent to the Honorable Earl W. Kintner, then Chairman of the Federal Trade Commission, over the signature of Senator Kefauver, Chairman of the Subcommittee. Upon information and belief, however, on that date and for the two weeks prior thereto Senator Kefauver was engaged in a primary campaign in the State of Tennessee. Senator Kefauver's subsequent statements on September 9, 1960, when the letter was called to his attention during the Subcommittee's hearings relating to antibiotics, would seem to indicate that he had little previous knowledge of it (Hearings on Administered Prices before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, pursuant to S. Res. 238, 86th Cong., 2d Sess., vol. 24, pp. 13,893-7). Upon information and belief the letter of July 19, 1960 was either prepared by Chairman Dixon or by someone on his staff at his direction or with his approval."

These appendices disclose that during a period beginning in 1959 and extending through 1960 (a time subsequent to the filing of the complaint by the Commission against petitioners in 1958) the subcommittee conducted an investigation of the drug industry, including the manufacture and sale of tetracycline. As Chief Counsel and Staff Director of the Subcommittee, Mr. Dixon played an active part in the investigation. These hearings were concerned specifically, among other things, with issues which were decided against petitioners by the Commission in the instant case and which are involved on the present petitions to review. The subcommittee received evidence relating to petitioners' prices for broad spectrum antibiotics, including tetracycline, to retailers, wholesalers, institutions and government agencies; costs and profits of petitioners; and proceedings before the patent office preceding the issuance of the tetracycline patent to Pfizer, including the interference settlement entered into between Pfizer and Cyanamid. Until the middle of March 1961, Mr. Dixon was in charge of and personally supervised all the investigatory activities of the Subcommittee's staff; participated in the selection of witnesses to testify and the documents to be introduced in evidence; and as an attorney conducted extensive examinations of witnesses in connection with factual issues involved in the present appeals. Chairman Dixon's memorandum (Appendix D) states that "as counsel, I played an active role in the accumulation and presentation of this factual data to the members of the Subcommittee."

Some of the questions and comments of Mr. Dixon as quoted in Appendix E demonstrate to us that he then had formed the opinion that tetracycline prices quoted by petitioners were artificially high and collusive and that the patent interference settlement between Pfizer and Cyanamid involved improper aid by Cyanamid to Pfizer in obtaining the tetracycline patent. Any opinions so formed

were conclusions as to facts, and not merely an "underlying philosophy" or a "crystallized point of view on questions of law or policy." The facts to which questions were directed as set forth in Appendix E are inseparably a part of the ultimate findings of fact of the Commission in disagreeing with the decision of the trial examiner in the present proceeding.

The letter of Senator Kefauver to the then Chairman of the Federal Trade Commission dated July 19, 1960 (Appendix B), expressed the view that the proposed findings of fact and conclusions of fact and law in the present proceedings "appear to be firmly based upon a large body of persuasive evidence" and that "I am confident that ultimately the Commission will reverse the hearing examiner's decisions." Petitioners charge that this letter was either prepared by Mr. Dixon or by someone on his staff at his direction or with his approval. This charge is not denied in the record before this court.

The report of the Subcommittee (S. Rep. No. 448, 87th Cong., 1st Session (1961)) contains the following language dealing with issues in the present case:

> "The most important and well-known example of the emergence of oligopoly from this process of mutual accommodation is the important antibiotic, tetracycline —manufactured by three of the leading drug companies and sold by five. . . . Moreover, it was touch-and-go whether the product was even patentable. To the intense distress of the companies, it developed that some quantities of tetracycline are obtained in the production of chlortetracycline—a fact which might well make the product unpatentable. The problem was further aggravated by laboratory and clinical tests which appeared to indicate that tetracycline is superior to its patented predecessors—chlortetracycline and oxy-

tetracycline. Under these circumstances the prospects of a repetition in the broad spectrums of what was so widely deplored in penicillin—free competition, falling prices and shrinking profit margins—appeared very real indeed.

"It was against this background that the companies *made their legal maneuvers with the twofold objective in mind—to assure the issuance of a patent and to secure the patent for themselves.*" Report, *supra*, p. 145.

• • •

"Although, under the earlier private agreement between Cyanamid and Pfizer, it was Pfizer who was to get the tetracycline patent, the latter could not act since no patent had yet been issued. Cyanamid then moved into the breach; on September 29, 1954, it instituted action against Bristol on the ground that Bristol's manufacture of tetracycline infringed Cyanamid's Aueromycin patent. . . .

"Pfizer, however, persisted in its submission of affidavits to overcome the rejection by the patent examiner, who asked if tetracycline could be shown to be present in Aureomycin 'in clearly identifiable form.' Pfizer scientists conducted tests purporting to prove that Aureomycin fermentation broth did not contain tetracycline. Using what Pfizer itself described as 'low potency' broth and 'commercial' tests, a negative result was secured, although the use of known sensitive tests would have shown the presence of identifiable tetracycline in the broth. In an affidavit submitted to the Patent Office, the Pfizer scientist swore that 'in fact there was no indication whatever of the presence of tetracycline'. This led the patent examiner to grant the patent to Pfizer. [File, U. S. Patent No. 2,699,054. *The validity of this assertion is a central point at*

issue in the FTC case, docket 7211, In the Matter of American Cyanamid et al.] On the same day separate infringement actions were instituted by the patentee against Bristol, Upjohn and Squibb.

"This set the scene for the end of the matter. On January 13, 1955, Cyanamid's infringement action against Bristol was settled with a license by Cyanamid for use of its Aureomycin patent in the manufacture of tetracycline. In return, Bristol agreed to pay royalties to Cyanamid on all of its sales of tetracycline." *Id.* at p. 146.

* * *

"Then suddenly the controversy was stilled. In March 1956 the six lawsuits then pending were privately settled in a series of agreements among the companies. . . .

"With the consummation of these arrangements, the *orderly and controlled* marketing of tetracycline was an inevitable and expected result. . . . all five have consistently sold at identical prices, . . ." *Id.* at p. 147. (Emphasis supplied).

The letter of Senator Kefauver transmitting the report to the Chairman of the Senate Committee on Judiciary expressed appreciation for the "efforts of Paul Rand Dixon, formerly counsel and staff director, and Dr. John M. Blair, chief economist, both in the work of the hearings on which this report is based and the assistance they rendered the Committee in the preparation of this report."

We do not find in the record before us a denial of the charge that Mr. Dixon, in his capacity as Counsel and Staff Director, assisted in the preparation of the report of the Senate Subcommittee, including the language above quoted.

We are not impressed with the Commission's argument that the proceedings before the Senate Subcommittee had

no relationship to the proceedings before the Commission because the former were "legislative" and "investigative" in nature. The record shows that the activities of the Subcommittee went beyond the scope of the ordinary legislative committee hearings. The report of the Subcommittee demonstrates that it extended its activities to the full limits of the Senate authorization, which included the power "to make a complete, comprehensive and continuing study and investigation of the antitrust and monopoly laws of the United States and their administration, interpretation, operation, enforcement and effect."

Under the facts and circumstances of this case we conclude that the participation of Chairman Dixon in the hearing "amounted . . . to a denial of due process which invalidated the order under review." *Texaco, Inc.* v. *Federal Trade Commission, supra,* 336 F.2d 754, 760 (C.A. D.C.), vacated and remanded on other grounds. 381 U.S. 739.

As said in *Amos Treat & Co.* v. *Securities and Exchange Commission,* 306 F.2d 260, 267 (C.A. D.C.):

> "[A]n administrative hearing of such importance and vast potential consequences must be attended, not only with every element of fairness but with the very appearance of complete fairness. Only thus can the tribunal conduct a quasi-adjudicatory proceeding meet the basic requirement of due process."

In *Trans World Airlines* v. *Civil Aeronautics Board,* 254 F.2d 90, 91 (C.A. D.C.), Judge Prettyman said:

> "It is plain that in this statute Congress contemplated an adjudicatory proceeding and conferred upon the Board in this respect quasi-judicial functions. The fundamental requirements of fairness in the performance of such functions require at least that one who participates in a case on behalf of any party, whether

actively or merely formally by being on pleadings or briefs, take no part in the decision of that case by any tribunal on which he may thereafter sit."

It is fundamental that both unfairness and the appearance of unfairness should be avoided. Wherever there may be reasonable suspicion of unfairness, it is best to disqualify. See *Prejudice and the Administrative Process,* 59 Nw. U. L. Rev. 216, 231 (1964); *Disqualification of Administrative Officials for Bias,* 13 Vand. L. Rev. 713, 727 (1960).

It is to be emphasized that the Commission is a fact-finding body. As Chairman, Mr. Dixon sat with the other members as triers of the facts and joined in making the factual determination upon which the order of the Commission is based. As counsel for the Senate Subcommittee, he had investigated and developed many of these same facts.

The result of the participation of Chairman Dixon in the decision of the Commission is not altered by the fact that his vote was not necessary for a majority. "Litigants are entitled to an impartial tribunal whether it consists of one man or twenty and there is no way which we may know of whereby the influence of one upon the others can be quantitatively measured." *Berkshire Employees Association of Berkshire Knitting Mills* v. *N.L.R.B.,* 121 F.2d 235, 239 (C.A. 3).

We therefore must vacate the order and decision of the Federal Trade Commission and remand the case for a de novo consideration of the record without the participation of Chairman Dixon. We reject the argument of the Commission that such a holding "would create an unworkable concept of administrative bias." Our decision on this issue goes no further than to hold that disqualification is required when, as in the present case, the legislative committee investigation involved the same facts and issues concerning

the same parties named as respondents before the administrative agency, and to the extent here presented. We do not hold that the service of Mr. Dixon as counsel for the subcommittee, standing alone, necessarily would require disqualification. Our decision is based upon the depth of the investigation and the questions and comments by Mr. Dixon as counsel, as shown by the record in this case, including Appendix E.

It has not been a rare occurrence in judicial history for an Attorney General or Solicitor General of the United States to be appointed to the Supreme Court. The practice of the justices so appointed in recusing themselves from participating in the decision of cases in which they were active while with the Department of Justice has not handicapped the President in making appointments of capable judges or created an "unworkable concept of judicial bias."

In holding that Chairman Dixon was disqualified to sit in this case, it is not the intention of this court to reflect in any way upon or question in the slightest degree the integrity, ability or dedication of the distinguished Chairman of the Commission.

The Issue as to the Jurisdiction of the Commission

For the assistance of the Commission on remand we deem it advisable to pass upon two additional issues that are pressed by the petitions to review: (1) whether or not the Commission has jurisdiction; and (2) whether the findings of the Commission with respect to the proceedings in the Patent Office involving the granting of the tetracycline patent are supported by substantial evidence.

The jurisdictional issue may be stated as follows: Assuming that a patent is obtained by misrepresentation and

improper conduct in the proceedings before the Patent Office, does the Federal Trade Commission have jurisdiction to hold that the subsequent use of such a patent for the purpose of excluding competition constitutes an unfair method of competition under Section 5 of the Act and, in fashioning a remedy, to order cumpulsory licensing of the patent upon a reasonable royalty basis? For the purpose of our discussion of the jurisdictional question we assume the facts to be as found by the Commission. The issue of the sufficiency of the evidence on this question will be discussed later in this opinion.

The Commission held as follows:

> "We are not holding that every misrepresentation of fact or withholding of material information before the Patent Office necessarily constitutes *per se* an unfair method of competition under the Federal Trade Commission Act. Some patents may be commercially worthless or have no adverse effects on competition. The facts of this case, however, are that a patentee has asserted monopoly rights under a patent so acquired and, as a consequence thereof, has restrained competition in the manufacture and sale of an important antibiotic; in at least one year the annual sales of tetracycline exceeded $100,000,000. The record further discloses that numerous drug houses have endeavored to enter the tetracycline market. All have been refused with the exception of respondents Cyanamid, Bristol, Squibb and Upjohn."

It is well settled that the Commission may exercise only the powers granted to it by the Act. *Federal Trade Commission* v. *National Lead Co.*, 352 U.S. 419, 428; *Federal Trade Commission* v. *Western Meat Co.*, 272 U.S. 554, 559. It is equally well settled that in enacting Section 5 of the Act Congress intended to make a broad delegation of power

to regulate and control unfair methods of competition. The legislative history shows that Congress intended to provide the Commission with broad discretion in interpreting Section 5:

> "It is impossible to frame definitions which embrace all unfair practices. There is no limit to human inventiveness in this field. Even if all known unfair practices were specifically defined and prohibited, it would be at once necessary to begin over again. If Congress were to adopt the method of definition, it would undertake an endless task." H.R. Rep. No. 1142, 63rd Cong., 2d Sess. 18-19 (1914).

As said by the Supreme Court in *Atlantic Refining Co.* v. *Federal Trade Commission*, 381 U.S. 357, 367:

> "Section 5 of the Federal Trade Commission Act declares "[u]nfair methods of competition in commerce, and unfair . . . acts or practices in commerce . . . unlawful." In a broad delegation of power it empowers the Commission, in the first instance, to determine whether a method of competition or the act or practice complained of is unfair. The Congress intentionally left development of the term 'unfair' to the Commission rather than attempting to define 'the many and variable unfair practices which prevail in commerce. . . .' S. Rep. No. 592, 63d Cong., 2d Sess., 13. As the conference report stated, unfair competition could best be prevented 'through the action of an administrative body of practical men . . . who will be able to apply the rule enacted by Congress to particular business situations, so as to eradicate evils with the least risk of interfering with legitimate business operations.' H. R. Conf. Rep. No. 1142, 63d Cong., 2d Sess., 19. In thus divining that there is no limit to business ingenuity and legal gymnastics the Congress displayed much foresight.

> See *Federal Trade Comm'n* v. *Cement Institute*, 333 U.S. 683, 693 (1948). Where the Congress has provided that an administrative agency initially apply a broad statutory term to a particular situation, our function is limited to determining whether the Commission's decision 'has "warrant in the record" and a reasonable basis in law.' *Labor Board* v. *Hearst Publications, Inc.*, 322 U.S. 111, 131 (1944). While the final word is left to the courts, necessarily 'we give great weight to the Commission's conclusion. . . .' *Federal Trade Comm'n* v. *Cement Institute, supra*, at 720."

Pfizer and Cyanamid contend that the Commission had no power to order the compulsory licensing of their patents. Pfizer asserts that the Commission has no jurisdiction to review the proceeding in the Patent Office, to attack indirectly the validity of a patent or to "second-guess the actions of the Patent Office." This is not a correct statement of the jurisdictional issue now before us. In the present case the Commission has not undertaken to pass upon the validity of the patents in question nor has it held the patents to be invalid. The order recognizes the validity of the tetracycline and aureomycin patents but compels licensing on what the Commission found to be a reasonable royalty basis. The Commission has not ruled that the act of obtaining the tetracycline patent by misrepresentation as such constituted a violation of Section 5, but rather that the subsequent use, for purposes of excluding competition, of a patent so obtained, constituted such a violation. It found that Pfizer has employed the tetracycline patent to suppress competition by suits and threats of suits against competitors and their customers and that Cyanamid also employed its patents as a weapon toward the common objective of suppressing competition. A list of thirty-six infringement actions filed by Pfizer against potential competitors and their customers is attached as Appendix F.

In its recent opinion in *Walker Process Equipment, Inc.* v. *Food Machinery & Chemical Corp.*, 382 U.S. 172, the Supreme Court said that the enforcement of a patent procured by fraud on the Patent Office may violate Section 2 of the Sherman Act, provided all other elements to establish a § 2 monopolization charge are proved, in which event the treble-damage provisions of § 4 of the Clayton Act would be available to the injured party. This case originated before a United States District Court, which indisputably has jurisdiction in such matters, and therefore is not controlling in the present case on the issue of the jurisdiction of the Commission. The reasoning, however, gives support to the decision of the Commission in the present case. The Court quoted with approval the following language from *Precision Instrument Manufacturing Co.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816:

> "A patent by its very nature is affected with a public interest. . . . [I]t is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope."

In his concurring opinion in *Walker Process Equipment, Inc.* v. *Food Machinery & Chemical Corp., supra,* Mr. Justice Harlan said:

> "To hold, as we do, that private suits may be instituted under § 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of

> the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, ***antitrust remedies should be allowed room for full play.***" (Emphasis supplied.) 382 U.S. 179-80.

In his concurring opinion in *United States* v. *Singer Manufacturing Co.*, 374 U.S. 174, 199-200, Mr. Justice White said:

> ". . . There is a public interest here . . . which the parties have subordinated to their private ends—the public interest in granting patent monopolies only when the progress of the useful arts and of science will be furthered because as the consideration for its grant the public is given a novel and useful invention. . . . When there is no novelty and the public parts with the monopoly grant for no return, the public has been imposed upon and the patent clause subverted. . . . [C]learly collusion among applicants to prevent prior art from coming to or being drawn to the Office's attention is an inequitable imposition on the Office and on the public. . . . In my view, such collusion to secure a monopoly grant runs afoul of the Sherman Act's prohibitions against conspiracies in restraint of trade—if not bad *per se*, then such agreements are at least presumptively bad."

To like effect see *Kingsland, Commissioner of Patents* v. *Dorsey*, 338 U.S. 318, 319; *United States* v. *United States Gypsum Co.*, 333 U.S. 364, 400.

The Federal Trade Commission Act may be construed *in pari materia* with the Sherman and Clayton Acts. "This construction allows for using cases decided under any of the antitrust laws in dealing with cases brought by the Commission." *Atlantic Refining Co.* v. *Federal Trade Commission*, 344 F.2d 599, 606 (C.A. 6), cert. denied, 382 U.S. 939.

The Federal Trade Commission Act contains no statutory exemption[10] of Patent Office proceedings, and we find nothing in the Act indicating any intention to set aside the Patent Office as a "city of refuge"[11] from the Commission's jurisdiction over unfair trade practices. Assuming that a Section 5 violation of the Act occurred, growing out of and following proceedings before the Patent Office in the present case, we hold that Section 5 of the Act confers jurisdiction upon the Commission with respect thereto. *Decker* v. *Federal Trade Commission*, 176 F.2d 461 (C.A. D.C.), cert. denied, 338 U.S. 878; *cf. Baldwin Bracelet Corp.* v. *Federal Trade Commission*, 325 F.2d 1012 (C.A. D.C.), cert. denied, 377 U.S. 923.

It is not accurate to accuse the Commission of "second guessing" the Patent Office. The Commission had before it evidence which it found to have been withheld from the Patent Office and passed upon a situation which the Patent Office never knew existed.

From our review of what was before the Commission in these proceedings, we are satisfied that it was within the competence of the Commission to adjudicate whether the total conduct of petitioners disclosed a violation of the Act. We hold that the Commission had jurisdiction to determine that the conduct of the parties before the Patent Office resulting in the issuance of the patent, and the subsequent use of the fruits of such conduct may, in total, be found to constitute violation of Section 5 of the Act.

Obviously there can be no question as to the jurisdiction of the Commission over the price fixing aspects of the case.

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[10] The Act excludes from the Commission's jurisdiction banks, common carriers subject to acts regulating commerce, air carriers and foreign air carriers, and persons subject to the Packers and Stockyards Act of 1921. 15 U.S.C. § 45(a)(6).

[11] Numbers 35:6.

As to the authority of the Commission to prescribe a remedy, the Supreme Court in *Atlantic Refining Co.* v. *Federal Trade Commission, supra,* said:

> "The Commission, of course, has 'wide discretion in its choice of a remedy deemed adequate to cope with . . . unlawful practices . . .' *Jacob Siegel Co.* v. *Federal Trade Comm'n*, 327 U.S. 608, 611 (1946). Furthermore, it acts within the limits of its authority when it bars repetitions of similar conduct with other parties. *Federal Trade Comm'n* v. *Henry Broch & Co.*, 368 U.S. 360, 364 (1962) . . .
>
> ". . . But Congress has placed in the Commission in the first instance the power to shape the remedy necessary to deal with unfair methods of competition. We will interfere only where there is no reasonable relation between the remedy and the violation. *Federal Trade Comm'n* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952)." 381 U.S. at 376-7.

As this court said in *Sandura Co.* v. *Federal Trade Commission*, 339 F.2d 847, 861 (C.A. 6):

> "Where there has been a continued course of unlawful price maintenance by agreement, however, it is within the discretion of the Commission to determine that the only effective way to terminate the effects of the unlawful conduct is by barring an otherwise lawful course of conduct which could have the practical effect of continuing the unlawful conduct unmitigated."

In the present case the Commission was not dealing with a patent on an ordinary item of commerce, but with patents on antibiotics of vital importance in the treatment and cure of many diseases and of tremendous impact upon the public health.

Compulsory licensing of patents by the courts for patent misuse is a permissable remedy in anti-trust cases. *Hart*

ford Empire Co. v. *United States,* 323 U.S. 386; 59 Nw. U. L. Rev. 543; 38 N.Y.U. L. Rev. 1191.

We accordingly hold that, assuming the facts as found by the Commission to be supported by substantial evidence, the Commission had jurisdiction to require as a remedy the compulsory licensing of the tetracycline and aureomycin patents on a reasonable royalty basis. We do not hold that the Commission has jurisdiction either directly or indirectly to invalidate or destroy a patent, nor do we hold that the Commission could order compulsory licensing without payment of reasonable royalties. We do hold that, in exercising its broad jurisdiction in the enforcement of Section 5 of the Act, the Commission could explore means and methods employed in obtaining the patents here involved and the subsequent use of the fruits thereof, assuming the other elements of a Section 5 violation.

The Substantial Evidence Issue

Because of our remand to the Commission, we do not express any opinion as whether or not the findings and decision with respect to the price-fixing issues are supported by substantial evidence.

For the assistance of the Commission, however, we are passing now upon the question of whether the findings with respect to misconduct in the proceedings before the Patent Office involving the granting of the tetracycline patent, and the use made of the fruits of such misconduct, are supported by substantial evidence.

The Commission's holding of improper conduct in the Patent Office proceedings is based upon its findings that false and misleading statements were made to the Patent Office and that material information was withheld, resulting in the granting of the tetracycline patent to Pfizer.

The findings of fact of the Commission must be accepted by this court if they are supported by substantial evidence

on the record considered as a whole. 15 U.S.C. § 45(c); *Atlantic Refining Co.* v. *Federal Trade Commission, supra,* 344 F.2d 599 (C.A. 6), cert. denied, 382 U.S. 939; *Sandura Company* v. *Federal Trade Commission,* 339 F.2d 849, 856 (C.A. 6).

In the present case the hearing examiner, who heard the testimony of the witnesses, found that no misrepresentations were made to the Patent Office by Pfizer, that the patent examiner was supplied with all the information which he requested and in which he was interested concerning the coproduction or inherent production of tetracycline, and that the patent examiner was not mislead or deceived by information withheld by either Cyanamid or Pfizer. The Commission disagreed with its hearing examiner and made findings of fact diametrically to the contrary.

Where the Commission overturns findings of fact of a hearing examiner, this conflict in fact finding is to be considered by a reviewing court. *Procter & Gamble Company* v. *Federal Trade Commission,* 358 F.2d 74 (C.A. 6), citing *Universal Camera* v. *N.L.R.B.,* 340 U.S. 474, 496, 497 and *N.L.R.B.* v. *Ohio Calcium Co.,* 133 F.2d 721 (C.A. 6).

In *United States Retail Credit Association* v. *Federal Trade Commission,* 300 F.2d 212, 217 (C.A. 4), the court said:

> "As we interpret the Universal Camera decision, the reviewing court is not prevented from considering the examiner's decision; if the agency's findings are not supported by substantial evidence, and if the examiner's findings are, the agency's findings must give way to those of the examiner. The examiner's findings are not sacrosanct; there is no mandate that the Commission accept them; they are but one portion of the entire record which the court is to consider in its review."

In *Benrus Watch Co.* v. *Federal Trade Commission*, 352 F.2d 313, 321 (C.A. 3), cert. denied, 34 U.S.L.Week 3391 (U.S. May 17, 1966), the court said:

> "While the findings of the Examiner were certainly not binding upon the Commission, they are part of the record, and are entitled to consideration in appraising the correctness of the ultimate findings of the Commission."

The details of the evidence will not be discussed at greater length than necessary in this opinion. Reference is made to the initial decision of the hearing examiner, which comprises 195 pages (see footnote 5), and the opinion of the Commission, which comprises 110 pages (see footnote 6).

Sufficient for the purposes of this opinion is the following summary, which is based principally upon, and sometimes stated verbatim from, the Commission's findings of fact.

Aureomycin (patented in 1949 by Cyanamid), terramycin (patented by Pfizer in 1950) and tetracycline are produced by the fermentation of microorganisms in aqueous nutrient media. The media are innoculated with the microorganisms and under controlled and aseptic conditions the microorganisms are allowed to grow. After a period of fermentation the antibiotics are recovered from the broth. For production on a commercial scale, the fermentation is conducted in large vats and the antibiotic substance is recovered and subjected to purification procedures in order to arrive at a product suitable for therapeutic use.

Aureomycin is made by the fermentation of a species of microorganism known as Streptomyces aureofaciens, hereinafter referred to as S. aureofaciens.

Tetracycline can also be produced by subjecting aureomycin to a process of mild catalytic hydrogenation, which

removes the chlorine atom from the aureomycin molecule. This chemical transformation was the original method by which tetracycline was discovered.

The patent covering aureomycin is the Duggar patent, U.S. Patent 2,482,055, issued September 13, 1949. (The Niedercorn patent, U.S. Patent 2,609,329, issued September 2, 1952, is an improvement patent on a process for producing aureomycin.) Both are owned by Cyanamid. The Sobin patent, U.S. Patent 2,516,080, covering the product terramycin, was issued to Pfizer on July 18, 1950; the Conover patent, U.S. Patent 2,699,054, covering tetracycline, was issued to Pfizer on January 11, 1955.

No company has been licensed by Cyanamid to sell aureomycin in the United States. Pfizer has been licensed to manufacture aureomycin for the limited purpose of converting it to tetracycline, and Bristol has been licensed to produce up to six per cent aureomycin in the production of tetracycline, and to sell tetracycline containing not more than six per cent aureomycin. Pfizer has licensed no company to produce or sell terramycin. As a result of their patents, Cyanamid and Pfizer have had a legal monopoly of the production and sale of aureomycin and terramycin, respectively. Pfizer has licensed Cyanamid and Bristol to manufacture and sell tetracycline, and has licensed Squibb and Upjohn to sell tetracycline.

Prior to 1952, the chemical structures of aureomycin and terramycin were unknown. During the spring of that year, a Pfizer research team headed by Dr. R. B. Woodward of Harvard University discovered the molecular structure of these two antibiotics. A member of the research team, Dr. Conover, noting the similarity in the structures of the two antibiotics, speculated that it might be possible to develop a new antibiotic by removing the chlorine atom from aureomycin. By subjecting aureomycin to mild hydrogenation by means of a catalyst such as pal-

ladium Conover removed the chlorine atom and, in June of 1952, produced tetracycline.

On August 8, 1952, an article by the Pfizer research team was submitted to the *Journal of the American Chemical Society* disclosing the formations and structures of aureomycin, terramycin and tetracycline. This article, referred to as the Stephens article, was published in the *Journal* on October 5, 1952.

On October 23, 1952, Conover filed an application for a patent claiming the product deschloroaureomycin (later called tetracycline), its salts, and a process for producing it by hydrogenation of aureomycin. On July 23, 1953, the Patent Office rejected the Conover application on the ground that the subject matter was obvious in the light of the aureomycin (Duggar) and terramycin (Sobin) patents, because of the similarity of the structural formulae of the three antibiotics.

On October 20, 1953, Pfizer filed a preliminary amendment to its patent application pointing out that the structures of aureomycin and terramycin were not known at the time of Conover's discovery of tetracycline. Thereafter, the patent examiner withdrew the rejection of the application on the aforementioned ground.

In 1948, Cyanamid had hydrogenated aureomycin and obtained a product which it later claimed was tetracycline. In December 1952, Cyanamid repeated its 1948 work and embarked upon a project in which tetracycline was produced from aureomycin by hydrogenation. On March 16, 1953, Cyanamid filed its Boothe-Morton application for a patent on tetracycline, its salts, and a process for manufacturing it by hydrogenating aureomycin.

On August 6, 1953, Cyanamid submitted an article to the *Journal of the American Chemical Society* describing the production of tetracycline by deschlorination of aureomycin. On August 13, 1953, Pfizer submitted a similar

article to the *Journal*. Both articles were published in the *Journal* on September 20, 1953. The disclosure of tetracycline and the process of deschlorination made possible the testing of previously unknown and unrecognized antibiotics, using the revealed tetracycline as a basis for comparison.

On September 25, 1953, the Heyden Chemical Corporation announced it had discovered an antibiotic, designated HA-20A, which might be tetracycline and that this antibiotic could be produced by direct fermentation. This announcement was the subject of an article which appeared in the *Journal of Commerce* on October 1, 1953. On September 28, 1953, Heyden applied for a patent (the Minieri application) on HA-20A, its salts, and a process for production thereof by fermentation using a newly discovered strain of S. aureofaciens and a mutant thereof.

On November 4, 1953, Cyanamid purchased Heyden's antibiotic facilities, including the rights to the Minieri tetracycline patent application.

H. J. Lidoff, the patent examiner handling the Cyanamid and Pfizer patent applications, declared an interference between these two applicants. Under Patent Office rules, an interference is a proceeding conducted for the purpose of determining priority between two or more applicants claiming the same invention.

The first interference was terminated on February 9, 1954, following the execution of the cross-licensing agreement between Pfizer and Cyanamid. Cyanamid conceded that the Pfizer (Conover) application had priority in time and withdrew its Boothe-Morton application.

On January 15, 1954, Bristol had filed continuation applications in the Heinemann matter, claiming tetracycline hydrochloride, and contending that this product was patently distinguishable from tetracycline.

On March 2, 1954, Examiner Lidoff declared a second interference. The parties to this interference were Pfizer Conover application), Bristol (Heinemann application) and Cyanamid (Minieri application which it had purchased from Heyden).

On October 14, 1954, Examiner Lidoff dissolved the second interference, ruling that the product tetracycline was not patentable, and rejected all product claims on the basis of coproduction, i.e. that the previously patented aureomycin process (Duggar and Niedercorn patents) inherently produced certain amounts of tetracycline. The Minieri application filed by Heyden on September 25, 1953, had disclosed that the microorganisms used to prepare tetracycline belonged to the species used in producing aureomycin and that aureomycin was coproduced in the Minieri fermentation process. On the basis of this information, the patent examiner speculated that tetracycline was coproduced with aureomycin in the processes disclosed in the Duggar and Niedercorn patents.[12] He also held that

[12] Examiner Lidoff stated in this connection:

"The interference count is unpatentable over the disclosures of Duggar U.S. 2,482,055, Sep't 13, 1949 and Niedercorn U.S. 2,609,329, Sep't 2, 1952, and the interference is dissolved. Duggar and Niedercorn each produce an antibiotic, disclosed as 'Aureomycin' by a fermentation process employing *Streptomyces aureofaciens* and mutants thereof. The antibiotic is identified as an antibiotic by assay against bacteria. It appears from the disclosure of Minieri et al (a party to this interference in an application available to all the parties) that tetracycline is *also* produced in such a fermentation process and that larger proportions thereof are produced when the amount of chloride in the fermentation medium is low . . . Minieri et al clearly and specifically disclose that the microorganism used to prepare *tetracycline* belongs to the Duggar et al U.S. 2, 482, 055 species and that 'the characteristics are identical with those exhibited by a known culture of *S. aureofaciens*'. While neither Duggar nor Niedercorn may have realized that tetracycline was in fact produced, they did appreciate and disclose that the product was an antibiotic. No invention is involved in the *identification* of the

tetracycline hydrochloride was not patently distinguishable from tetracycline.

On November 29, 1954, Pfizer's patent representatives met with Examiner Lidoff in his office concerning the rejection of the Conover application on the ground of the unpatentability of tetracycline because of inherent production. The statements made at this interview and the affidavits and statements made concerning experiments conducted as a result of this interview encompass most of the misrepresentations which the Commission found Pfizer to have made in its successful effort to persuade Examiner Lidoff to change his decision.

A written summary of this interview contains the following recitation:

> "At the outset of the interview, the Assistant Examiner agreed that the discovery of the new antibotic, tetracycline (and its salts), constituted a major advance in the art, that should merit patent protection. He further conceded that neither the Duggar nor the Niedercorn patents contains any disclosure whatsoever of this important new antibiotic nor the slightest hint as to the possible existence thereof. However, he stated that applicant's product claims appeared to be anticipated by the possible, although wholly unappreciated, co-production of appreciable amounts of tetracycline in the fermentation processes described in the cited patents.
>
> "It was pointed out to the Assistant Examiner that there is no reasonable basis for his speculation as to

---

tetracycline and its hydrochloride inherently produced by the reference process (see In re Lieser 1947 C.D. 447; and Allen et al v. Coe 1943 C.D. 55). It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the count (see Parke-Davis v. Mulford 189 F 95 and In re Kebrich 96 US PQ 411)."

the co-production of tetracycline in the prior art processes, and that the same rejection had previously been made and withdrawn in the prosecution of the Heinemann, et al. application. . . . The Examiner, however, felt that he was justified in relying upon the disclosure of the Minieri et al. application Serial No. 382,637 as giving rise to a rebuttable assumption of inherent production.

"Applicant's counsel denied that any such prima facie assumption is justified. . . .

"The available evidence is overwhelmingly contrary to the Examiner's assumption. Minieri et al themselves, in their brief on their motion to add fermentation counts in the interference . . . have stated that tetracycline could previously be produced only by deschlorination, and that there is no evidence of inherent production by the prior art processes. Most striking of all is the fact that the assignee of the Duggar and Niedercorn et al patents, who manufactured literally tons of chlortetracycline (Aureomycin) according to the methods described therein, failed to discover any tetracycline in such large-scale manufacture, although it devoted extensive research to the recovery, purification and properties of its patented antibiotic. Said assignee first claimed tetracycline (and its salts) made by a *deschlorination* process in its Boothe et al application Serial No. 342,556 filed March 16, 1953, some five years after the Duggar and Niedercorn patents were filed. This should conclusively refute the tenuous basis for the Examiner's unwarranted assumption.

* * *

"Despite the foregoing arguments, the Examiner adhered to his position that he would not withdraw his rejection of the product claims, unless applicant sub-

mits a showing overcoming his speculated basis for such rejection. He explained that he would require evidence that fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the deposited strain NRRL-2209, do not contain recoverable amounts of tetracycline. He stated that the absence of such amounts of tetracycline would have to be established by failure to recover this antibiotic in a clearly identifiable form according to present day efficient methods for the separation thereof from fermentation broths.

"While applicant's counsel did not concede that there is any necessity for such a showing, he ventured the opinion that it could be made and stated that he would explore the matter in view of the great urgency of this case. The Examiner made it clear that he would not insist on a categorical averment that the fermentation broths prepared according to the cited patents contain no tetracycline whatsoever. He evidently appreciates the impossibility of proving its non-existence and is not concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic."

The Niedercorn (aureomycin) patent contained forty-four examples of media. Lidoff asked Pfizer to run some tests on Example 28, which appeared to contain only a trace of chloride ion. The Commission found as a fact that "It is evident, however, that the examiner was interested in the possible production of tetracycline in any of the Niedercorn examples."

Pfizer thereupon conducted tests to determine whether tetracycline could be recovered from Duggar and Niedercorn Example 28 broths, using the three recovery procedures described in the Bogert-Walsh, Minieri and Heinemann applications.

Pfizer submitted affidavits to Examiner Lidoff, executed by two of its scientists, Bogert and Tanner, reporting unsuccessful efforts to recover products clearly identifiable as tetracycline from the Example 28 fermentation broths. After examining these affidavits, Mr. Lidoff requested more information as to the possibility of recovering tetracycline. The next day, December 9, Pfizer representatives conferred again with Mr. Lidoff and submitted a supplemental affidavit signed by Bogert, in which the following conclusion was expressed:

> "Based on these results and on his experience with the results of a great many such tests on materials containing tetracycline, chlortetracycline and mixtures thereof, he is convinced that not nearly as much as 20% of the potency of the amorphous material could be due to the presence of tetracycline, in fact there was no indication whatever of the presence of tetracycline. Assuming that the maximum possible proportion of the total potency due to tetracycline is 10%, this means that the 0.36 grams of amorphous material cannot contain more than about 0.009 grams of tetracycline. He does not know of any method whereby any part of such a minute amount of tetracycline could be separated and recovered in clearly identifiable form from the amorphous material."

Cyanamid representatives had told Examiner Lidoff earlier that, outside of experiments in fermenting tetracycline directly, Cyanamid had no knowledge that there had ever been any coproduction of tetracycline in broths which were intended to produce aureomycin. The Commission found that Cyanamid discovered later, and prior to the issuance of the tetracycline patent, that there had been coproduction of tetracycline in aureomycin broths, but failed to disclose this fact to Examiner Lidoff.

On December 9, 1954, after receiving the Pfizer tests and affidavits, including Bogert's supplemental affidavit filed the previous day, Examiner Lidoff granted a notice of allowance to Pfizer. Under Patent Office procedure, a patent normally issues within a month after the notice of allowance.

On January 3, 1955, six days before the tetracycline patent was issued to Pfizer, Bristol filed with the Patent Office an affidavit disclosing in detail the fact of the presence of from two per cent to four per cent tetracycline in old aureomycin. Nevertheless the patent was issued to Pfizer on January 9.

Fundamental to the Commission's findings of improper conduct on the part of Pfizer and Cyanamid is the question of to what extent previous coproduction of tetracycline in aureomycin broths was material to the issuance of the patent. This involves numerous questions concerning the actions and purposes of Examiner Lidoff as representative of the Patent Office, the answers to which are so uncertain that the Commission reached conclusions directly contrary to the findings of its hearing examiner, based upon the same evidence.

There are numerous instances of sharp disagreement between the Commission and its hearing examiner as to findings of fact relating to the actions and purposes of Examiner Lidoff, examples of which are set forth in Appendix G.

Many material questions are not answered clearly by the evidence in the record before us, such as:

To what extent was Examiner Lidoff aware of inherent coproduction of tetracycline in aureomycin broths and in the finished product?

Was he concerned only about coproduction in aureomycin as a finished product, or was his inquiry also directed to coproduction in aureomycin fermentation broths?

Was the hearing examiner correct or incorrect in his finding that if Lidoff had known that old aureomycin contained from two to five per cent of tetracycline, he nevertheless would have granted the patent?

Did Lidoff consider any amount of coproduction under ten per cent to be immaterial?

Why did Lidoff request tests by Pfizer of Niedercorn Example 28, rather than requesting tests of others of the forty-four Niedercorn examples, at least one of which (Example 1) the Commission found would have disclosed five per cent coproduction?

Was Lidoff interested in establishing only that the prior art processes did or did not produce tetracycline in "appreciable" amounts, making possible its prior recovery as a therapeutic product? Was this his purpose in setting up the test of Example 28? If so, what did he consider to be an "appreciable amount" of tetracycline?

Was the hearing examiner correct in his conclusion that Lidoff knew "for more than a year prior to the decision on the second interference that fermentation broths produced under Dugger and Niedercorn usually contained tetracycline," or was the Commission correct in its conclusion to the contrary?

Did Lidoff draw a distinction as to the significance of coproduction as between product and process applications, as found by the hearing examiner, or was the Commission correct in reaching its contrary conclusion?

Did Lidoff see the "Taylor affidavit" filed by Bristol January 3, 1955, six days before the patent was issued? If so, what significance did he attach to its contents?

Would Lidoff's decision to grant the patent have been different if Cyanamid had revealed that it was in error in its prior assurances that there was no coproduction of tetracycline in aureomycin? Or was he already aware of the

facts which the Commission found to have been withheld by Cyanamid?

Finally, the ultimate questions are: Did Lidoff receive all the information that he requested from Pfizer? And was Lidoff mislead and deceived by Pfizer and Cyanamid and did he grant the tetracycline patent as the result of such deception?

It would seem that the answers by Examiner Lidoff to these questions might settle conclusively the issue as to whether Pfizer and Cyanamid made misrepresentations to the Patent Office and withheld essential information, thereby deceiving Lidoff into granting a patent which otherwise never would have been approved.

Only Examiner Lidoff could have answered these questions. Yet the Commission failed to call him as a witness, although requested by petitioners to do so during the hearings. Instead the Commission introduced as a witness Mr. Manuel C. Rosa, Lidoff's superior in the Patent Office, who obviously could not answer questions concerning matters which were exclusively within the personal knowledge of Examiner Lidoff. Petitioners did not seek to subpoena Examiner Lidoff to testify as their witness, having been denied an opportunity to interview him in advance.

It is said that it would be against the policy of the Patent Office to have permitted Lidoff to testify as a witness in these proceedings.

The Patent Office Manuel of Patent Examining Procedure, § 1701, provides as follows:

> **"1701 Examiners Not To Express Opinion on Validity Nor Testify as Patent Experts**
>
> **"Inasmuch as public policy does not permit Examiners to decide, as judges in the Patent Office, questions upon which they have been retained to give**

opinions as expert witnesses in patent cases in the courts, every Examiner who shall testify as an expert in a patent case pending in any court will be dismissed, unless he shall have so testified involuntarily, upon compulsion by competent judicial authority, and without retainer or preparation. (Basis: Notice of March 6, 1880.)

"Congress, in 35 U.S.C. 282, has endowed every patent granted by the Patent Office with a presumption of validity. Public policy demands that every employee of this Office refrain from expressing to any interested person any opinion or view as to the invalidity of any U.S. Patent. The question of validity or invalidity is exclusively a matter for the courts to determine. Each member of the examining corps is cautioned to be especially wary of any inquiry from any person outside the Patent Office (including any employee of another government agency), the answer to which might indicate that a particular patent should not have been issued.

"Whenever an examiner is asked or subpoenaed to testify in a suit concerning a patent, trademark registration, or application for either, he is directed to report that fact *immediately* to the Solicitor. (Basis: Notice, May 4, 1959.)

"Examiners are cautioned against answering inquiries from any person outside the Patent Office as to whether or not a certain reference was considered and, *a fortiori*, whether or not a claim would have been allowed over that reference. This applies to anything in the patented file, including the extent of the field of search and any entry relating thereto. The record of a patented file must speak for itself. Practitioners can be of material assistance in this regard by refraining from making such inquiries of members of the examin-

> ing staff. Answers to inquiries of this nature must of necessity be refused, and such refusal should be considered neither discourteous nor an expression of opinion as to validity. (Basis: Notices of May 18, 1961 and October 21, 1960.)
>
> "Also, Examiners are reminded that, in view of the long established policy of the Patent Office to refuse to permit members of the staff of the Patent Office to testify in patent suits, they should, before allowing an application, determine that the written record is accurate and complete."

We see no reason why Examiner Lidoff could not have been subpoenaed as a witness to testify as to facts known only to him with respect to material issues of great public interest in this proceeding.

With no testimony available from Mr. Lidoff, the hearing examiner and Commission drew opposite inferences and reached opposite conclusions as to what this patent examiner knew, intented, and required in the processing of the patent applications. We find the decision of the Commission on this issue to be based upon inferences and speculation which are insufficient to constitute substantial evidence. See *Universal Camera Corp.* v. *N.L.R.B., supra,* 340 U.S. 474, 496; *N.L.R.B* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300.

Accordingly we hold that paragraphs three through eight of the final order of the Commission, and its decision to the effect that the tetracycline patent was issued as a result of improper conduct on the part of Pfizer and Cyanamid, are not supported by substantial evidence on the record considered as a whole.

This opinion is not to be construed as an approval by this Court of the initial decision of the hearing examiner.

The entire proceeding is remanded to the Commission for a de novo hearing on all issues without the participation of Chairman Dixon. Upon rehearing the Commission may consider any evidence previously taken and now on file and such additional evidence on any issue raised by the complaint as may be admissible and relevant to such issues. Any party shall be accorded the right to require the presence of any previously sworn witness for additional testimony either on direct or cross-examination.

Vacated and remanded.

First Opinion of Court of Appeals, 363 F.2d 757

APPENDIX A

Pfizer's Affidavit in Support of Motion to Disqualify Chairman Dixon

UNITED STATES OF AMERICA
BEFORE
FEDERAL TRADE COMMISSION

[SAME TITLE]

STATE OF NEW YORK,)
) ss.:
COUNTY OF NEW YORK,)

JOHN E. F. WOOD. being duly sworn, deposes and says:

1. I am a member of the firm of Dewey, Ballantine, Bushby, Palmer & Wood, attorneys for the respondent Chas. Pfizer & Co., Inc. This affidavit is submitted in support of the motion of said respondent that the Honorable Paul Rand Dixon, Chairman of the Federal Trade Commission, be disqualified from participating in the hearing or determination of the appeal of counsel supporting the complaint from the Initial Decision herein or in other action of the Commission in this proceeding. This affidavit is based on the record of "Hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, on Administered Prices in the Drug Industry", 86th Cong., 1st and 2nd Sess., vols. 14-26 (1959-60), and S. Rep. No. 448, 87th Cong., 1st Sess. (1961).

2. From February 1957 until he became Chairman of the Commission on or about March 16, 1961, Mr. Dixon

served as Counsel and Staff Director of the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary of the United States Senate.

3. In 1959 and 1960 the Subcommittee conducted an investigation into the manufacture, pricing and sale of the broad spectrum antibiotics which are the subject of this proceeding, and of other ethical drugs. In the course of the investigation the Subcommittee requested and received documents and information from the respondents and others relating to many aspects of the manufacture, distribution and sale of broad spectrum antibiotics, including pricing, bulk sales and purchases, requests for bulk supplies, patents, patent licenses, requests for such licenses, and patent interference settlements. Some of the material thus received by the Subcommittee is a part of the record in this proceeding; a part of such material, however, is not in the record of this proceeding although it relates to matters at issue herein. Mr. Dixon was in charge of the investigating activities of the Subcommittee staff, including those relating to broad spectrum antibiotics.

4. In September 1960 the Subcommittee held a number of hearings relating primarily to broad spectrum antibiotics. The testimony was quite extensive, the transcript consisting of almost 4,000 pages. Mr. Dixon participated actively in these hearings, examined many of the witnesses and introduced a large number of exhibits. The hearings were in effect an adversary proceeding in which some witnesses adverse to the ethical drug industry were called to testify, and some representatives of the industry, including representatives of the respondents, were subjected to questioning in the nature of cross-examination.

5. During these hearings some of the very transactions and issues involved in this proceeding, which are now to be considered by the Commission on the appeal from the

Initial Decision, were the subject of extensive testimony and documentary evidence. Thus, the hearings dealt at some length with respondents' prices to wholesalers, retailers and institutions (Hearings, pp. 13,657-72, 13,729-39) respondents' bids and sales to the Military Medical Supply Agency (Hearings, pp. 13,687-94, 13,702-04, 13,715-19, 13,779-82, 13,790-92, 13,800-04); the interference settlement entered into between Pfizer and Cyanamid on January 11, 1954 (Hearings, pp. 13,694-702); and the infringement litigation, including the settlement thereof, between Pfizer on the one hand and Bristol, Squibb and Upjohn on the other (Hearings, pp. 13,905-06, 13,910-15).

6. During these hearings, on issues which are involved in the present proceedings, Mr. Dixon advocated positions which are inconsistent with the findings and conclusions of the Hearing Examiner which are now to be reviewed by the Commission.

(a) After a detailed review of the respondents' bids and prices to the Military Medical Supply Agency (MMSA) and other federal agencies, the Hearing Examiner found that "The record demonstrates price competition in the Federal market." (Initial Decision, p. 168). On the other hand, the line of Mr. Dixon's questioning of representatives of the respondents and other witnesses on this subject was apparently based on the contrary view (Hearings, pp. 13,687-94).

(b) After reviewing all the evidence, the Hearing Examiner rejected as "without merit" the contention of counsel supporting the complaint that the respondents had agreed upon a division of the MMSA market (Initial Decision, pp. 166-67). Mr. Dixon, on the other hand, in the presentation of evidence on this subject before the Subcommittee, referred to facts upon which counsel supporting the complaint had relied and char-

acterized them as an "unusual occurrence" which called for explanation (Hearings, pp. 13,702-04).

(c) The Hearing Examiner has found that there were good and non-conspiratorial business reasons for different prices to the MMSA and the Veterans Administration (Initial Decision, pp. 164-65). Mr. Dixon's questioning on this subject before the Subcommittee, however, suggested the view that the differences between the prices quoted to the two agencies were a cause for suspicion (Hearings, pp. 13,716-19).

(d) One of the subjects considered in detail by the Hearing Examiner was the interference settlement between Pfizer and Cyanamid. He found that the parties were actuated by sound and legitimate business reasons, that Pfizer was entitled to the concession of priority which it received and that there was no basis in the evidence or in logic for inferring that Cyanamid was seeking to help Pfizer obtain the patent (Initial Decision, pp. 24-26, 121-22). Mr. Dixon's questioning on this subject before the Subcommittee, however, indicated a considerably less favorable view of the interference settlement (Hearings, pp. 13,695-98).

(e) Although counsel supporting the complaint had sought to show that there was an agreement restricting Bristol's sales of bulk tetracycline to Squib and Upjohn, the Hearing Examiner found to the contrary and specifically found that "Bristol's license [from Pfizer] contained no restrictions on bulk sales and authorized it to sell to whomever and wherever it wanted without restriction" (Initial Decision, p. 77). At the hearings before the Subcommittee, however, when a witness testified to the same effect, Mr. Dixon produced a document which is in evidence in this proceeding and which he contended was inconsistent with the statement of the witness (Hearings, pp. 13,913-14).

7. On May 8, 1961, Senator Kefauver transmitted to the Chairman of the Committee on the Judiciary a report of the Subcommittee on Antitrust and Monopoly entitled "A Study of Administered Prices in the Drug Industry" (S. Rep. No. 448, 87th Cong., 1st Sess. (1961)). His transmittal letter stated:

> "I want to acknowledge with appreciation the efforts of Paul Rand Dixon, formerly counsel and staff director, and Dr. John M. Blair, chief economist, both in the work of the hearings on which this report is based and in the assistance they rendered the committee in the preparation of this report."

8. The Report contained a number of legal and factual conclusions concerning issues in this proceeding, some of which are inconsistent with the findings and conclusions of the Hearing Examiner which are now to be reviewed by the Commission.

(a) The Report (at pages 89-92) discusses at some length the respondents' bids to the MMSA. The Report adopts the conclusions suggested during Mr. Dixon's presentation of evidence (see par. 6(a) above). It refers to certain price fluctuations as "strange price behavior" and specifically quotes critical remarks made by Mr. Dixon with respect to this price behavior. It refers to the claimed division of the MMSA market as "another 'astounding' coincidence."

(b) The Report (at pages 145-47, under the heading "Oligopoly") surveys the interference settlement between Pfizer and Cyanamid, the subsequent proceedings in the Patent Office, the litigation and settlement between Cyanamid and Bristol, and the litigation and settlement between Pfizer on the one hand and

Bristol, Upjohn and Squibb on the other. These matters were considered in great detail by the Hearing Examiner and, as to each of them, the Initial Decision is to the effect that the parties acted properly and lawfully. The tenor of the Report is different. It presents these matters as questionable both in their motivation and their effect.

9. Another expression of opinion on matters which are in issue in this case was contained in a letter dated July 19, 1960 which was sent to Honorable Earl W. Kintner, then Chairman of the Federal Trade Commission, over the signature of Honorable Estes Kefauver, Chairman of the Subcommittee (Hearings, p. 15,831). This letter, it is submitted, may be taken as reflecting the views not only of Senator Kefauver but also of the staff members, including Mr. Dixon, who worked so closely with him. The letter, after complimenting counsel supporting the complaint "for having done such an excellent job", proceeded to an appraisal of their proposed findings and conclusions in this case in the following terms:

> "* * * It appears to be firmly based upon a large body of persuasive evidence; the issues involved are presented understandably; and the whole document is written clearly and to the point."

The view that the presentation of counsel supporting the complaint "appears to be firmly based upon a large body of persuasive evidence" is directly contrary to the conclusion of the Hearing Examiner, which is now to be reviewed by the Commission, to the following effect:

> "* * * The decision must be based upon reliable, probative and substantial evidence upon consideration of the whole record. By such standards, counsel support-

ing the complaint have not sustained their burden of proof. Based upon a consideration of all the reliable, probative and substantial evidence in the record, it is concluded and found that the respondents have not engaged in any of the violations alleged in the complaint." (Initial Decisions, p. 194.)

10. On the facts set forth above it is respectfully submitted that Mr. Dixon, as Counsel and Staff Director of the Subcommittee, has participated in investigations of and hearings upon matters which are in issue in this case and has advocated positions inconsistent with the Initial Decision which is now to be reviewed by the Commission.

JOHN E. F. WOOD

Sworn to before me this
12th day of December, 1961:

ROBERT W. ALBERTS
Notary Public

ROBERT W. ALBERTS
Notary Public, State of New York
No. 60-0033725
Qualified in Westchester County
Certificate filed with N. Y. Co. Clerk
Term Expires March 30, 1963

APPENDIX B

Letter Written by Senator Estes Kefauver to the Chairman of the Federal Trade Commission dated July 19, 1960.

"The Honorable Earl W. Kintner
Chairman
Federal Trade Commission.
Washington 25, D.C.

Dear Chairman Kintner:

I have read with great interest the *Proposed Findings of Fact and Conclusions of Fact and Law,* Docket 7211, in the matter of American Cyanamid *et al.,* involving the antibiotic, tetracycline. I wish to take this opportunity to compliment the Commission, and particularly Mr. Goodhope and the other staff members who prepared the document, for having done such an excellent job. It appears to be firmly based upon a large body of persuasive evidence; the issues involved are presented understandably; and the whole document is written clearly and to the point.

There is, however, one aspect of the matter which troubles me. I am referring to decisions by the hearing examiner to keep *in camera* economic information on market shares, percentage markups, costs and profits of the respondents. (Cf. Proposed Findings 67, 68, 69, 99, 100, 101)

If the hearing examiner's decisions are allowed to stand, a dangerous precedent would be established under which the Congress, scholars and the public generally would be denied knowledge of the bases on which much of the enforcement of Section 7 will turn. In this connection I cannot help but note that the court did not feel it incum-

bent to keep *in camera* information on market shares in the proposed Bethlehem-Youngstown merger. Nor has the Commission in its enforcement of Section 7 felt itself so obligated. As to the cost data, the courts and the Commission have long records of making such information available where relevant to the issues involved in the litigation, as is certainly the case here. In this connection may I call attention to the importance played by cost data in the *Aluminum* case. This decision was spceifically cited in the legislative history as one which Congress intended the amended Section 7 'to go beyond.' It would seem anamalous for the Government to have included data in the public record in a Sherman Act proceeding but not to be able to do so in a proceeding under a newer and broader statute.

For these and related consideration, I am confident that ultimately the Commission will reverse the hearing examiner's decisions which, the record indicates were strongly objected to by the Commission's trial counsel.

But here a problem of timing arises. The Senate Subcommittee on Antitrust and Monopoly plans to resume its inquiry into the drug industry with hearings on antibiotics in late September or early October. In view of the amount of time granted by the hearing examiner to counsel for the respondents, it is most unlikely that the matter of the hearing examiner's decision on the *in camera* issue would reach the Commission in the regular course of events for decision until well after our Subcommittee hearings have been completed.

Under these circumstances I am hereby requesting the Commission under Section 1.134 of its *Rules of Practice, Procedure and Organization* to make available to the Subcommittee for the purpose of inspection, copying and use, the material in the proposed findings referred to above, in

furtherance of the Subcommittee's inquiry into the drug industry.

In view of the pressure of time, your early consideration of this matter would be greatly appreciated.

Sincerely yours,

Estes Kefauver,
Chairman"

APPENDIX C

Commission's Interlocutory Order of December 20, 1961, Denying Motions to Disqualify Chairman Dixon.

(Reported at 59 Federal Trade Commission Decisions 1488)

UNITED STATES OF AMERICA
BEFORE
FEDERAL TRADE COMMISSION

COMMISSIONERS:

Paul Rand Dixon, Chairman
Sigurd Anderson
William C. Kern
Philip Elman
Everette MacIntyre

[SAME TITLE]

All of the respondents in this proceeding have individually presented motions requesting the Commission to disqualify Commissioner Dixon from participating in the appeal from the Initial Decision of the hearing examiner. These motions, filed under Section 7(a) of the Administrative Procedure Act, 5 U.S.C. § 1006(a), are based on an alleged prejudgment of the issues of fact and law to be presented in the appeal.

Section 7(a) of the Administrative Procedure Act clearly empowers the Commission to determine whether a presiding officer conducting a "hearing" on behalf of the Commission is subject to "personal bias or disqualification." It is less clear that it was meant to apply to participation of individual agency members in final or

appellate determinations. The inquiry called for by a motion for disqualification is necessarily subjective in nature. It is extremely difficult and delicate for a tribunal to assume the responsibility of weighing, objectively, the ability of one of its own members to make an objective judgment in a case. Further, the existence of such a power to disqualify carries with it an inherent danger of abuse, as a potential instrument for suppression of dissent.

Under the Commission's practice, disqualification is treated as a matter primarily for determination by the individual member concerned, resting within the exercise of his sound and responsible discretion. The Commission believes this practice to be proper and consistent with the law. In the instant proceeding, no basis for departing from the normal practice has been shown.

IT IS ORDERED, therefore, that respondents' motions be, and they hereby are, denied.

By the Commission, Commissioner Dixon not participating.

Joseph W. Shea,
Secretary.

Issued: December 20, 1961

APPENDIX D

Memorandum of Chairman Dixon in Regard to Motions that He Be Disqualified.

(Reported at 60 Federal Trade Commission Decision 1881.)

UNITED STATES OF AMERICA

BEFORE

FEDERAL TRADE COMMISSION

[SAME TITLE]

By separate motions supported by affidavits the respondents herein have requested that I be disqualified from participating in this proceeding. All of the motions were filed pursuant to Section 7(a) of the Administrative Procedure Act and allege in substance that my prior position and duties as Counsel and Staff Director of the Antitrust and Monopoly Subcommittee of the Committee on the Judiciary of the United States Senate disqualify me from further participation in this matter.

As the motions disclose, the Subcommittee for which I acted as Counsel and Staff Director did, during 1959 and 1960, conduct an investigation, including public hearings, into certain pricing and other practices of the ethical drug industry. As leading members of that industry, the respondents herein were requested to, and did, furnish documents and other information to the Subcommittee. As counsel, I played an active role in the accumulation and presentation of this factual data to the members of the Subcommittee.

While the motions inaccurately describe the role I played in the aforesaid investigation as "advocacy," it

should be unnecessary for me to point out that hearings before Congressional committees are *ex parte* and in no sense adversary in nature. Further, they cannot be said to be adjudicative, since they have as their sole purpose the amassing of facts in order that the Congress may be adequately informed concerning the desirability or need for legislation. The entire extent of my participation in the Subcommittee's investigation of the ethical drug industry is a matter of public record. I stand on that record but, of course, do not consider myself bound by the writings or statements of others who participated in that investigation, including Subcommittee members or employees.

My duties with the Subcommittee staff definitely did not involve the making of decisions or judgments on the facts accumulated. It was my duty to assist in adducing all of the facts with respect to the subject being investigated and to refrain from presenting only one side of controversial subjects.

Respondents' motions refer to the phrasing of questions which I directed to witnesses during public hearings before the Subcommittee as indicating my advocacy of positions opposed to those of the respondents herein. It is elementary that the questions of a lawyer engaged in eliciting facts from a witness do not necessarily indicate his state of mind but are couched in terms best calculated to adduce the truth.

The points raised by the respondents against my participation in this proceeding are not unlike the charge of bias raised against the complete membership of the Commission in the case of *Federal Trade Commission* v. *Cement Institute, et al.*, 333 U.S. 683 (1948). In that case, after the taking of testimony had been concluded and while the proceeding was still pending before the Commission, one of the respondents asked the Commission to disqualify itself from passing upon the issues involved, alleging that the

Commission had previously prejudged the issues and was prejudiced and biased against the Portland cement industry generally. The Commission refused to disqualify itself, and the contention was subsequently presented to and rejected by both the Circuit Court of Appeals for the Seventh Circuit and the Supreme Court. Because the situation there dealt with is so analogous to the situation in which I now find myself and because the Supreme Court's consideration of this point is so clear and so complete, I quote from that opinion (pp. 700-702, *supra*):

> "Marquette introduced numerous exhibits intended to support its charges. In the main these exhibits were copies of the Commission's reports made to Congress or to the President, as required by § 6 of the Trade Commission Act. 15 U.S.C. § 46. These reports, as well as the testimony given by members of the Commission before congressional committees make it clear that long before the filing of this complaint the members of the Commission at that time, or at least some of them, were of the opinion that the operation of the multiple basing point system as they had studied it was the equivalent of a price fixing restraint of trade in violation of the Sherman Act. We therefore decide this contention, as did the Circuit Court of Appeals, on the assumption that such an opinion had been formed by the entire membership of the Commission as a result of its prior official investigations. But we also agree with that court's holding that this belief did not disqualify the Commission.
>
> "In the first place, the fact that the Commission had entertained such views as the result of its prior *ex parte* investigations did not necessarily mean that the minds of its members were irrevocably closed on the subject of the respondents' basing point practices.

Here, in contrast to the Commission's investigations, members of the cement industry were legally authorized participants in the hearings. They produced evidence—volumes of it. They were free to point out to the Commission by testimony, by cross-examination of witnesses, and by arguments, conditions of the trade practices under attack which they thought kept these practices within the range of legally permissible business activities.

"Moreover, Marquette's position, if sustained, would to a large extend [*sic*] defeat the congressional purposes which prompted passage of the Trade Commission Act. Had the entire membership of the Commission disqualified in the proceedings against the respondents, this complaint could not have been acted upon by the Commission or by any other government agency. Congress has provided for no such contingency. It has not directed that the Commission disqualify itself under any circumstances, has not provided for substitute commissioners should any of its members disqualify, and has not authorized any other government agency to hold hearings, make findings, and issue cease and desist orders in proceedings against unfair trade practices. Yet if Marquette is right, the Commission, by making studies and filing reports in obedience to congressional command, completely immunized the practices investigated, even though they are 'unfair,' from any cease and desist order by the Commission or any other governmental agency.

"There is no warrant in the Act for reaching a conclusion which would thus frustrate its purposes. If the Commission's opinions expressed in congressionally required reports would bar its members from acting in unfair trade proceedings, it would appear

that opinions expressed in the first basing point unfair trade proceeding would similarly disqualify them from ever passing on another. See *Morgan* v. *United States,* 313 U.S. 409, 421. Thus experience acquired from their work as commissioners would be a handicap instead of an advantage. Such was not the intendment of Congress. For Congress acted on a committee report stating: 'It is manifestly desirable that the terms of the commissioners shall be long enough to give them an opportunity to acquire the expertness in dealing with these special questions concerning industry that comes from experience.' Report of Committee on Interstate Commerce, No. 597, June 13, 1914, 63d Cong., 2d Sess. 10-11.

"Marquette also seems to argue that it was a denial of due process for the Commission to act in these proceedings after having expressed the view that industry-wide use of the basing point system was illegal. A number of cases are cited as giving support to this contention. *Tumey* v. *Ohio,* 273 U.S. 510, is among them. But it provides no support for the contention. In that case Tumey had been convicted of a criminal offense, fined, and committed to jail by a judge who had a direct, personal, substantial, pecuniary interest in reaching his conclusion to convict. A criminal conviction by such a tribunal was held to violate procedural due process. But the Court there pointed out that most matters relating to judicial disqualification did not rise to a constitutional level. *Id.* at 523.

"Neither the *Tumey* decision nor any other decision of this Court would require us to hold that it would be a violation of procedural due process for a judge to sit in a case after he had expressed an opinion as to whether certain types of conduct were prohibited

by law. In fact, judges frequently try the same case more than once and decide identical issues each time, although these issues involve questions both of law and fact. Certainly, the Federal Trade Commission cannot possibly be under stronger constitutional compulsions in this respect than a court.

"The Commission properly refused to disqualify itself. We thus need not review the additional holding of the Circuit Court of Appeals that Marquette's objection on the ground of the alleged bias of the Commission was filed too late in the proceedings before that agency to warrant consideration."

Should I accede to the respondents' motions here, I might also find myself barred from consideration of cases in other industries investigated while I served as Counsel and Staff Director to the Senate Antitrust and Monopoly Subcommittee of the Committee on the Judiciary. These industries include, among others, the steel, automobile, milk, bread and roofing industries. I would thus find myself in the position where my experience acquired from working as a legislative counsel would be a handicap instead of an advantage. This, in my opinion, would defeat the very intendment of Congress in creating a Commission to be manned by commissioners with some degree of expertise.

Following the respondents' contentions to their ultimate conclusion, the Commission itself might be alleged to be disqualified from ultimately judging a proceeding because of the fact that, under its basic responsibilities, it reviews, prior to the issuance of a complaint, investigational records. Such investigational records are not unlike investigative records of legislative bodies. They are both *ex parte*. However, after the issuance of a complaint by the Commission and the joinder of issues, it is clear that the pro-

ceedings then become adversary and the record must be finally judged in this climate. I find myself in a position not greatly different from that of my fellow Commissioners.

The respondents' motions are founded upon the assumption that I have prejudged the issues here involved, and I am incapable of rendering an impartial decision. Thus, what is here involved is the present state of my mind with respect to these issues. The state of a man's mind is by the nature of things known only to him and to his Maker. I have carefully and conscientiously considered the question here presented and have concluded, and hereby state, that I have not formed a definite opinion with respect to any of the material issues involved in this proceeding and honestly believe that I have a free and open mind with respect thereto, and I am fully capable of rendering a completely impartial decision based solely upon the facts contained in the record. Accordingly, I shall not withdraw from participation in this proceeding.

In view of the nature of these motions, I am not participating in the Commission's deliberations and decision upon them.

PAUL R. DIXON
Paul Rand Dixon,
Chairman.

FILED: February 1, 1962.

EXHIBIT E

Excerpt from hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, on Administered Prices in the Drug Industry, 86th Congress, 1st and 2nd Sessions, Vol. 24 (1959-1960), in which Mr. Paul Rand Dixon participated as Chief Counsel and Staff Director.

Dr. Blair. May I, Mr. Chairman, make a point which will only take a second? Dr. Malcolm brought up the point of the increase in the cost of labor and the increase in the cost of equipment. All I want to observe is that undoubtedly those increased costs of labor and equipment were also applicable to both streptomycin and penicillin.

Dr. Malcolm. I would like, since you revived the subject, to say that the entire industry would go bankrupt if we attempted to sell the broad spectrum drugs at penicillin prices.

Mr. Dixon. You mean that if you were to be competitive, you would go bankrupt?

Dr. Malcolm. Many people did go bankrupt.

Mr. Dixon. Are you against competition?

Dr. Malcolm. No, sir. I think we have the highest form of competition.

* * *

Mr. Dixon. Mr. Chairman, before you go to the next table, in your statement in the first paragraph, Mr. Duncan, you said, when you were tracing the price reduction down to 1951:

The price had declined to a point where it was well within the reach even of the needy.

I recall the statement by Dr. Malcolm, in tracing how quickly people get well today as compared to yesterday, that usually when this drug was prescribed, it has been from $8.50 to $17. For anybody who has had this experi-

ence—and I do not think there is anybody in this room who has not had to have an antibiotic prescribed for himself, or a member of his family—do you think a cost of $17 to the average mother and father every time their child has a bad cold is down to a point where it can be reached even by the needy?

Mr. Duncan. First of all, as Dr. Malcolm has pointed out—I have raised a family of four children so I can speak with authority—you normally do not encounter resistant organisms. In my case, and I have had a number of cases, you have one course of antibiotics which is $8. Now I consider with all the other expenses that are involved in raising a family, $8 is not a particularly large sum to spend on something of this kind, and the typical experience is unless you are particularly unfortunate that you need antibiotics about once or twice in your entire lifetime. You are talking about—it is not as much as the cost of a pair of shoes, you know.

Mr. Dixon. Mr. Duncan, I do not mean to dispute you. But I have two children; one is 10 and the other 13. They have on the average of two or three colds a year, and every time they have a bad cold, they get a prescription for antibiotics, and it is always refilled. I think I am not much different from the average person; my children are pretty healthy. We receive thousands of letters that do not agree with what you say.

* * *

Senator Kefauver. Mr. Dixon, will you proceed?

Mr. Dixon. Thank you, Mr. Chairman.

Dr. Malcolm, with respect to Aureomycin, you did sell this product, I believe to the Military Medical Supply Agency in the past; is that correct, sir?

Dr. Malcolm. That is correct, Mr. Dixon.

Mr. Dixon. We examined some of the exhibits that were received, and data that was obtained from MMSA and

presented in the Federal Trade Commission case. Then we received data from MMSA to confirm it.

So taking a 250-milligram tablet in bottles of 100, we found, starting from 1951 down through 1959, your company selling Aureomycin, Parke, Davis, selling Chloromycetin, and Pfizer, selling Terramycin. In 1951 you sold to MMSA in the range between $18 and $15.30; Parke, Davis sold between the range of $20 and $15.30; and Pfizer sold between the range of $19.50 and $15.

In 1952, you sold to MMSA at $15; Parke, Davis, $15.30; Pfizer, $15.

In 1953, you sold at $15; Parke, Davis, at $12.50; and Pfizer, at $15; and so on, until, say. 1958, when you sold at $11; Parke, Davis, in the range of $12.50 and $11.25; and Pfizer, between the range of $10.97 and $10.75.

It is my understanding from talking to this agency that they bought these supplies on what they call negotiated bids; is that correct, sir?

Dr. Malcolm. I think that is correct.

Mr. Dixon. And from what I have pointed out to you, it is obvious that the price came down over that period of time.

Do you have any recollection of your company making any difference in a price quotation to this agency on a volume purchase?

Dr. Malcolm. Mr. Dixon, I am not qualified to answer your question on that because I do not have the facts. May I refer that, Mr. Chairman, to Mr. Duncan, who is general manager of the division?

Senator Kefauver. All right, very briefly, go ahead, Mr. Duncan.

Mr. Duncan. Yes.

Mr. Dixon, I think you will find generally—I don't have the figures in front of me—generally speaking, the MMSA,

or Armed Services Procurement Agency, normally bought in very large quantities, you are correct.

They normally bought bottles of 100 or 250 milligrams in very large quantities. I believe the quantities normally ranged from 40,000 to 50,000 bottles and some of them ran as high as 75,000 or 80,000 bottles.

Mr. Dixon. I note that in 1956 your range to the Military Medical Supply Agency for Aureomycin, 250-milligram tablets, bottles of 100, was between $11 and $12.

Mr. Duncan. Yes; I believe it came from $12 down to $11.

Mr. Dixon. And at this same time your price to the druggist was $30.60.

Mr. Duncan. That is correct.

Mr. Dixon. When tetracycline came into the field and the Military Medical Supply Agency began to purchase this product—Mr. Chairman, I would like to ask that this exhibit be made exhibit 21 in the record.

Senator Kefauver. It will be made 21.

(Exhibit No. 21 follows:)

* * *

Mr. Dixon. This reflects the purchases from negotiated bids made by the Military Medical Supply Agency from October 1956, through December 1959.

You will note in October 1956, on the quantity that was asked for, the total price of the purchase of 94,176 bottles was $1,035,936. The winning price was $11. This was the unit price of Lederle Laboratories. You will notice that Bristol Laboratories bid $18.97. Pfizer bid $19.58. Squibb bid $19.58, also.

This is an identical product that you bid on. All three were manufacturing and making it, isn't that correct, sir?

Mr. Duncan. That is right.

Mr. Dixon. If you will go down to the next bid, May 14, 1957, it was a $155,232 purchase, and it went to Charles

Pfizer & Co. for $11, the unit price. On this quantity you bid $19.58, as Squibb bid $19.58. Why on this particular bid did you bid identically with Squibb?

Mr. Duncan. That was our published price, the Federal Government published price. The first time we bid was in October 1956, isn't that correct, $11? As I recall the circumstances, up to that time I think the buying had been entirely Aureomycin or Terramycin with some Chloromycetin, but the real competing products there were Aureomycin and Terramycin.

Now what happened was I was not fully aware of this, being a little new in the business, that the Army had never before bought tetracycline.

It was brought to my attention that they had an order for tetracycline. Well, I guess I did not give it a great deal of consideration.

That was just about the time that I was just looking at. This matter came up with the Federal Trade Commission, so I was trying to refresh my memory.

* * *

Mr. Dixon. Looking at that document again, if you will, sir, you will note that you and Pfizer changed places. On the first bid you bid $11 and you were awarded the bid. The next time you raised your price and Pfizer lowered their price to $11.

Mr. Duncan. They obviously thought we were going to bid $11 again or a little more than $11.

Mr. Dixon. I notice that $11 mistake never occurred after the first two times.

Mr. Duncan. I can't speak for Pfizer, but you will find from that time on we have a published Government price which we bid regularly.

We came to the conclusion on tetracycline at least that was a reasonable price for Army bidding and we would

stick to that price, so any further bids you see are prices which you will find in our catalog.

Mr. Dixon. If you will run your eye on down—

Senator Kefauver. You wouldn't bid $11 unless you could make some money on it, would you?

Mr. Duncan. No, when we come down to $11, Senator, what you have to consider is that if you consider the regular costs which normally apply and should apply on a business of that type, you lose money at $11, and if you try to apply that kind of price for our total business, you will see we would quickly go bankrupt.

Mr. Dixon. If you will go down the list of various purchases, you said from that time on you started bidding $19.58. This appears to be true. But you will note, for instance, in February 1958 Pfizer was bidding $17.24. You will notice again in March of that year you bid $17.24. Upjohn, in January of 1958, had bid $14, but you were still bidding $19.58.

Why did you keep on bidding $19.58 as long as you had already found out that at least on a big order in June 1958, of $1,611,526, previous experience had shown that Pfizer was willing to bid $17.24? Pfizer bid $17.24 again and got the award. You kept your price at $19.58.

Mr. Duncan. We did not choose to meet that competition. We felt that we just were not justified in doing it. We held to our published Federal Government price in 1958. Eventually we decided to come down and meet it and our current price is $17.60 less 2 percent or a net of $17.24.

Mr. Dixon. On the very next bid after that, September of 1958, for $361,000 and some odd cents, all of the companies bid $17.24 other than Bristol, which was rejected. How come you bid $17.24 on that one? Is that when you started meeting competition?

Mr. Duncan. We had simply decided at that time that we would move our Federal Government price down to that price, published it, and bid that figure.

Mr. Dixon. So the other companies had done the same thing because that was awarded by lot?

Mr. Duncan. I cannot really say. I do not really know what they did. I had no idea what they were going to bid but I decided I was not going to compete on that basis for the business. We would have a regular Government price that we would adhere to and which we have adhered to.

Mr. Dixon. I notice that they all bid $17.24. Nobody was at $17.23 or $17.25. You were all at $17.24. This was a change for you. Where did it come from so far as you were concerned?

Mr. Duncan. The previous bid. If you go back here, and that $17.24 had been bid by Pfizer as early as January of 1958. You see, after everyone of these awards, we get all the bids by the various companies and we know what they are doing. That had been bid as early as January 14, 1958.

Mr. Dixon. So all you have to do is go to the bid opening and find out what the others bid and if one bid less than that before, if you want to be competitive, you just adopt that price, is that it?

Mr. Duncan. Not necessarily. You have to make up your mind as to what you want to do and I am sure the others may not be exactly in our position. As I say, the—

Mr. Dixon. If you really wanted the business, why didn't you bid $17.20?

Mr. Duncan. I had not the faintest idea, Mr. Dixon—it is very easy looking back, but in looking ahead, I had not the faintest idea. Actually, I was astounded that they bid $17.24. I expected someone to bid, with a different situation, to bid $15 or $16. I had no idea what those bids would be.

Mr. Dixon. You knew if Pfizer repeated for $17.24 and you bid $17.24, you would be matched. You knew that?

Mr. Duncan. Yes.

Mr. Dixon. And you would not get the order unless you drew it by lot, isn't that true?

Mr. Dixon. But if you really wanted it, you could have bid $17.20?

Mr. Duncan. Yes.

Mr. Dixon. Pfizer also bid $17.24.

Mr. Duncan. You are assuming a fact that was evident only after the bids were open. At that time my question was, Was it worth while trying to shade off a few pennies when the likelihood was one of our competitors would bid $2 under that figure or $3 under that figure?

If you go back to the bidding on aureomycin and terramycin, that is exactly what happened. We bid $1.50 or $2 under and then Pfizer bid $2 under and we bid $2 under and we got this price down to a ridiculous figure.

Mr. Dixon. If you will just move down to the next one on that list, you will find that Squibb came with a $17.15 bid. Obviously, Squibb wanted it because the rest of you bid $17.24.

Mr. Duncan. We were just bidding our published price. Why our competitors did not bid $1, $2, or $3 under that, I cannot explain. I know nothing about it.

Mr. Dixon. Are you saying this price that was originally $19.58 was published and then you published the $17.24 price, also?

Mr. Duncan. That is correct.

Mr. Dixon. Each time you change it, you published it?

Mr. Duncan. I am sure that is correct. We were bidding our published price, because that has been our fixed policy since that time.

Mr. Dixon. What published price is this? Where do you publish a price? You are only going to sell to MMSA. Do you publish a price to them in advance?

Mr. Duncan. I am sure we do. It is a Federal Govern-

ment price that I believe is published in our catalog, is it not?

Mr. Hesse. Yes, all Government agencies.

Mr. Duncan. It is general knowledge. There is no secret about it.

Senator Kefauver. If that is the case, there is not much use in the MMSA asking for bids, if you are all going to have the same price.

Mr. Duncan. The history has been that it has not been the same price. I cannot answer for the other companies. As far as I am concerned, we decided that this would be our policy, and what they bid was none of our concern.

Mr. Chumbris. May I ask a question at this point? For clarification of the record on the exhibit in front of us, I notice that the first two bids on the top of the page are listed as ADV, under "Method."

Mr. Dixon. That means advertised instead of negotiated. Advertised means secret bid.

* * *

Mr. Dixon. From my recollection from the statements that have been made, reference was made to the fact that tetracycline was brought on the market and that your company had done a great deal of work on it. About the time you brought it out you found others were bringing out a similar or an identical product. I assume, Dr. Malcolm, that when you brought this product out, you made application for a patent; did you not?

Dr. Malcolm. Yes.

Mr. Dixon. Did I understand you to say you had made application?

Dr. Malcolm. Yes; we made application for both process and product patent.

Mr. Dixon. After you made application, you found others had made application; did you not?

Dr. Malcolm. That is true.

Mr. Dixon. How many of them made an application?

Dr. Malcolm. Well, it is a rather involved story.

Mr. Dixon. If you will just name them, that is all I want.

Dr. Malcolm. Well, there were about two applications. One was concerned with a product patent for tetracycline produced by the process of dechlorination. Another application was made which was concerned with a process or processes of producing tetracycline by fermentation, and being related to tetracycline hydrochloride. That was the second application.

Mr. Dixon. Because more than one application had been made, under the regular procedure at the Patent Bureau it was placed in an interference procedure, was it not?

Dr. Malcolm. That is correct, sir.

Mr. Dixon. Is it not true that this patent was ultimately issued to Pfizer?

Dr. Malcolm. That is correct.

Mr. Dixon. What kind of an arrangement did you make with Pfizer when you withdrew from this interference?

Dr. Malcolm. We made no arrangement. We drew up some cross licensing agreements between Aureomycin whereby we agreed to license them to manufacture Aureomycin for the purpose of manufacture tetracycline solely, and they, in turn, in the event they received a patent, whoever received the patents on tetracycline would cross license each other. However, Mr. Dixon, that is a matter that was gone into very thoroughly in Federal Trade Commission testimony.

Mr. Dixon. I don't mean to pursue it in depth, sir. I just want this background.

On the other hand, you had this interference on this important tetracycline product, and the interference was withdrawn and Pfizer obtained a patent. Wasn't that roughly about it?

Dr. Malcolm. No, the interference was not withdrawn. In the fall of 1953, I think it was, an interference was declared between Pfizer and ourselves for the production of tetracycline by the—

Mr. Dixon. Did your company withdraw from the interference?

Dr. Malcolm. We withdrew in this sense, and you must be very careful as to how you use the word "withdraw." It was agreed between Pfizer and ourselves that the evidence as to priority would be submitted to a third party, or to third parties, to determine which party was prior in terms of invention. These independent parties determined that Pfizer was the prior inventor, and so, therefore, we withdrew. In the event that there had been any difficulty, we proposed submitting these data to the Patent Office itself.

Mr. Dixon. But as I understand, that is the function of the Patent Office, so you just worked out an independent process.

Dr. Malcolm. No, no. Of course, I am not a patent attorney, but I think that the procedure that was followed is common procedure.

Mr. Dixon. The fact is that Pfizer received the patent, and by this arrangement you had entered into with them you became a licensee?

Dr. Malcolm. That is right. Pfizer ultimately got the patent both for product and process, and we became a licensee of Pfizer's for tetracycline under the tetracycline patent which they hold, and we in turn licensed them under our Duggar patents for the manufacture of Aureomycin for decholorination in the production of tetracycline.

Mr. Dixon. The point I want established is that at the time the patent was awarded to Pfizer, there was no other application before the examiner to pass upon, was there?

Dr. Malcolm. Well, to the best of my knowledge there was no other application before the examiner at the time the patent was issued to them.

Mr. Dixon. This is my point.

* * *

Senator Kefauver. You can say yes or no, whether that is a correct statement. You and Bristol had an application for the patent, along with Pfizer. By some arrangement or another, you got out anyway, you were out, and the same happened to Bristol. Then immediately afterward Pfizer licensed you and Bristol.

Dr. Malcolm. No, Mr. Chairman, that isn't so; and I can't answer your questions yes or no because they are highly involved questions. If you will permit me to proceed, perhaps I can explain it to you in a matter of 5 minutes.

Mr. Dixon. I thought you had previously told us, Dr. Malcolm, at the time before you went to arbitration—

Dr. Malcolm. Pardon me?

Mr. Dixon. I thought you had just told us before you went to arbitration that you worked out arrangements with Pfizer where you agreed to license—

Dr. Malcolm. There are two parts to the agreement. In the fall of 1953, Mr. McKeen, who is president of Pfizer, came to see me and asked if we were parties to the tetracycline interference, which dealt with the dechlorination process and the product patent itself.

I told him that we were, and he said that they were also in the interference. Now, this is the first declared interference. In this one there was just Pfizer and ourselves.

It is of interest as to why I think a settlement was reached and as to why Pfizer came to us. Going back to the fall or the spring of 1953, we were having difficulties with our Aureomycin, competitive difficulties in terms of the acceptance of it, due to what was claimed to be excessive side effects. So I had asked our research people and devel-

opmental people to see if there was something they could do with regard to lessening these undesirable side effects.

We did a great deal of work on this when one day—again in early spring, is the time I am referring to—one of our research men came in and said that he had produced tetracycline by removing the cholorine from the Aureomycin molecule. We sent the tetracycline out; we performed a pharmacological and toxicity test and sent it out for clinical study, and we were very happy and pleased to learn that tetracycline had not only about the same bacteriological spectrum but it lacked these undesirable characteristics that had been associated with Aureomycin. Then we made patent application in the spring of 1953 under the name of Booth & Morton, I think it was, claiming the product and the process of dechlorination. Then later that fall, my associates, research associates, told me that an article had appeared in a journal, a chemical journal, a scientist by the name of Stevens, who was an employee of Pfizer, had postulated the structure of chlortetracycline and tetracycline. I remembered this at the time of my meeting with Mr. McKeen, and Mr. McKeen made it very evident that he felt that they had the dominating patent position in terms of the interference.

I tried to convince him that we had the dominating position. At the same time, I was somewhat concerned because of the Stevens article, which had postulated the structure of tetracycline, that they probably had priority.

Now, we in the meantime had put tetracycline on the market as a superior product. We had committed ourselves to it and we had actually passed the point of no return in terms of Aureomycin. Now, commercially, aside from the scientific facts, that is very important. That was very important to us, because Mr. McKeen had Terramycin, and if he obtained the patent, the product and process patent, he could stop us from manufacturing tetracycline, to which we

had committed ourselves, but, of course, Mr. McKeen could not manufacture tetracycline without infringing our Duggar patents.

So under such circumstances, I could not afford to take the commercial risk which might endanger our entire market. As I recall having said, in the Federal Trade Commission, Mr. McKeen had me over a barrel, and I wanted to get off of that barrel.

So after giving it thorough consideration, I agreed with Mr. McKeen on two agreements. One, that we would license him under our Duggar patents for him to make Aureomycin for the sole purpose, and we would give him know-how to do it, but for the sole purpose of making tetracycline.

As a part of that agreement, Mr. McKeen insisted that we sell to him bulk tetracycline.

Now, certainly, it wasn't in our interest, after having introduced tetracycline and having done the original clinical work on it, to put Mr. McKeen in business. That certainly would have been most stupid on our part.

But he insisted upon this, that we do furnish him with bulk tetracycline. So I had to accede to that request.

So then the matter of the first interference came up insofar as priority is concerned, and the purpose of that, of course, was to determine who was the prior inventor. As we said earlier, we had these independent people who determined that priority belonged to Pfizer.

Mr. Dixon. Who were these individuals?

Dr. Malcolm. One of them was our counsel, Mr. Watson, I believe, who is a very distinguished patent man; Mr. Edelblute, who is a patent attorney for us.

• • •

Senator Kefauver. You had agreed that Pfizer would license you, and you, in turn, would give them the Duggar

license so they could make chlortetracycline, and that you would sell to them in bulk.

Dr. Malcolm. No, Mr. Chairman. Whoever was prior, that if we got the patents—I still was hopeful. I didn't know who had priority in this, but I was hopeful that we would get the patents on the tetracycline process and product.

But whoever got it, the agreement was that we would license—cross-license each other on the basis of the commercial risk that was involved.

Senator Kefauver. This sounds like your attorney and Mr. McKeen's attorney getting together and making a decision.

Dr. Malcolm. That wouldn't represent good business sense, Mr. Chairman.

Senator Kefauver. It was an outside arbitration?

Dr. Malcolm. It wasn't an outside arbitration. This was done, as I understand it, by attorneys representing us and attorneys representing them.

Senator Kefauver. And your attorneys agreed that they had priority?

Dr. Malcolm. And our attorneys—I was notified by—

Senator Kefauver. I must say that is the most remarkable arbitration I have ever heard of.

Dr. Malcolm. No. Again, I am not a patent attorney but I am told that this is most common.

Mr. Dixon. The reason I asked you to digress and give us that background is because I want to refer you now to exhibit 21 which shows the purchases by the Military Medical Supply Agency from those producers of tetracycline. Tetracycline, I have been informed, is the largest selling item.

As I understand the development of tetracycline, Pfizer did ultimately obtain the patent. You and Bristol Labora-

tories were licensed to manufacture and sell tetracycline. I do not understand—

Dr. Malcolm. You mean by Pfizer?

Mr. Dixon. Sir?

Dr. Malcolm. By Pfizer?

Mr. Dixon. Yes, by Pfizer.

Dr. Malcolm. Yes.

Mr. Dixon. I understand that Squibb and Upjohn were licensed merely to sell and not manufacture tetracycline.

Dr. Malcolm. I don't really know. Of course, that would be no concern of ours. That would be a matter between—

Mr. Dixon. But you do know that there were, and are, five sellers of tetracycline?

Dr. Malcolm. That is correct.

Mr. Dixon. I have named all five of them.

Dr. Malcolm. Yes, that is true.

Mr. Dixon. Mr. Chairman, I have another table here which I would like to suggest be made exhibit No. 22.

Senator Kefauver. Does this have to do with this patent matter?

Mr. Dixon. It does, sir.

Senator Kefauver. All right, let it be made exhibit No. 22.

* * *

Mr. Martin. Mr. Chairman, may I say something on this remark that was made some time ago that the settlement of the interference between Pfizer and Cyanamid was a very unusual procedure.

It is a very common procedure in interference proceedings not only in the drug field but in the chemical field, and I think if your staff will look at a good many of the documents that were submitted by us in answer to the subpena, that you will find a good many of them contain similar provisions as to setttlements of interferences.

Senator Kefauver. The only thing that appeared unusual to me was that Dr. Malcolm was presenting the reasons why he had the prior and superior claims to the patent on tetracycline. Mr. McKeen was doing the same. And how the lawyer for Dr. Malcolm could get together with the lawyer for Mr. McKeen and both of them decide against Dr. Malcolm and Lederle—you call that an arbitration? I don't understand.

Mr. Martin. I don't call it an arbitration myself, Mr. Chairman, but it was a common way of settlement, and if there had been disagreement as to the facts—and this was a determination of a fact of priority of invention—provision was made in the agreement for submitting the facts to the Patent Office for their determination.

Senator Kefauver. It looks to me as if the agreements for cross-licensing, whichever way it went, played an important part in pressing the case for a patent.

Mr. Martin. I don't follow that reasoning.

Senator Kefauver. In other words, Dr. Malcolm had already agreed with Mr. McKeen that Mr. McKeen would license him or he would license Pfizer, whichever way it went, but that if Pfizer received the patent, however Pfizer would insist on tetracycline being sold to them in bulk. Part of the agreement was that Lederle would license Pfizer to make chlortetracycline, so that the matter was arranged, it seems to me, to protect both sides, whichever way the decision went.

Mr. Martin. There was one thing there that the agreement provided, the separate agreement:

That we would furnish the bulk whether we got the patent on tetracycline or whether he got it. It was not that we would sell him if he got the patent; and if we got the patent, we were to get a royalty from Pfizer; and we would very much have desired to get that royalty.

Senator Kefauver. Part of the agreement also was that you would get a royalty on chlortetracycline from them, whichever way it went?

Mr. Martin. We had that patent which was long in existence, and we had a royalty payable to us from Pfizer no matter which way the interference was decided.

Senator Kefauver. Have these agreements been made a part of the record of the Federal Trade Commission case?

Mr. Martin. Yes, sir; they have.

Senator Kefauver. We can make note of them.

Dr. Malcolm. This is one of the key issues.

Mr. Chairman, as you probably have discerned, Mr. Martin is trained as a lawyer. The legal department and patent department, among many other things, report to him. I am not. But from a strictly business standpoint, Pfizer and ourselves were in a mutual blocking situation; and, if a settlement was not made, tetracycline could not have been made available to the public or sold at all so long as that situation continued to exist.

Senator Kefauver. The unfortunate thing about it is that there is quite a question whether tetracycline should have been patented in the first place. Unless you had agreed to let one side or the other have it, it might have been that the Patent Commissioner would have not issued a patent. In that case, small manufacturers could have made the product and competed.

Mr. Martin. That is quite a question that is before the Federal Trade Commission, and I think it is a little pressing us to go into the details of that any further, Mr. Chairman.

Senator Kefauver. I won't insist that you do, but I am just stating how it appears to me: by working out this agreement, you made it easy for a patent to issue and both of you got what you wanted; but this made more or less moot the question of whether a patent should issue at all or not.

It is possible the Patent Commissioner may have decided the matter the other way: that no patent should issue.

We have that situation right now in the case of prednisone, where there are several interferences, and it is quite possible that the Commissioner in that situation would decide that no patent should issue and all the little companies can then compete.

Mr. Martin. Under the patent system, Mr. Chairman, when we conceded priority because of the facts of—

Mr. Dixon. Arbitration?

Mr. Martin. No; no arbitration. It was not arbitration.

It was discussion between counsel of Pfizer and counsel of Cyanamid, to put the facts upon which they would rely in the Patent Office on the table, and our counsel advised us that he had to concede priority because Pfizer was prior.

Our conceding priority in that interference immediately threw us out of the interference and we had no knowledge of any further prosecution of that patent, because after the interference was dissolved by the examiner, it became an ex parte proceeding again and we know nothing about what went on in the Patent Office between Pfizer and the Patent Office.

Senator Kefauver. It is a whole lot easier to get a patent issued when there is an ex parte proceeding—just one person—than it is when there is a contest as to whether it is patentable or not, and, if so, who should have the priority.

Mr. Martin. The contest in the priority proceeding, where there is an interference, is an assumption that the Patent Office has decided that the claims are patentable, but they wish to decide the priority between the two claimants, and that is what the interference is declared for.

Senator Kefauver. Dr. Malcolm, you never would have agreed to this kind of an arrangement about submitting it to counsel and letting them decide it unless you had had a firm commitment from Pfizer that they would license you in the event it was decided their way.

Dr. Malcolm. Mr. Martin is pointing out that the agreement was signed before we submitted it to counsel.

Senator Kefauver. But you never would have gone along with this procedure by which Pfizer won the patent unless they had previously agreed to license you.

Mr. Martin. There is a difference there. It is not whether the patent would issue. It was whether one party was prior to the other.

That was the question that we were settling, and we were settling that if one party was determined to be the junior party and therefore not entitled to priority, that party would concede priority to the other.

Senator Kefauver. This is a matter of semantics.

Mr. Martin. No, sir.

Senator Kefauver. Then let's restate it.

Dr. Malcolm, you never would have agreed to this method of deciding who had priority—that is, you would have gone on and fought the case through—except for the fact that you already had an agreement that Pfizer would license you and you were going to be taken care of?

Dr. Malcolm. No, the only reason I was interested in that agreement was, as I explained before, I was fearful that Pfizer had priority, which turned out to be true. And from a commercial standpoint, regardless of semantics or anything else, I did not dare take the risk of losing that position.

Senator Kefauver. That is the point I was making: If you had not had the agreement, you would have fought on because you did not dare take the risk of losing.

Dr. Malcolm. I could have fought on, but as the facts ultimately proved to be, I would have lost.

In the meantime, I would have been stopped from the manufacture of tetracycline and I also would have been subject to considerable royalty payment, I am sure of that.

Senator Kefauver. I think it should be pointed out that

in this case and in other similar cases, one of the facts brought to the attention of the Patent Commissioner is whether a patent should be issued in the first place; that is, whether a product is patentable when you bring up new facts about it; whereas, when it is just an ex parte proceeding, then the opposing party is not there to bring out these facts to the attention of the Commission.

But, anyway, we have talked about this matter long enough. Let us proceed.

Mr. Dixon. Mr. Chairman, I call the witness' attention to the exhibit which you have just put in the record, exhibit 22. We asked the Military Medical Supply Agency to supply this information to us. You will note there that Agency's procurement of tetracycline in all forms between November 1956, and October 1959. On the top are listed the sellers: Pfizer, Lederle, Bristol, Squibb, Upjohn, then the total. You will notice in the left column the forms in which it was sold. You will note the percentages at the bottom. That is arrived at by adding these columns of purchases from each individual company. In this period of time on the total purchases of tetracycline from the five sellers, Pfizer was successful in 46.6 percent of the dollar value of the purchases; Lederle was successful in 17.8 percent of the dollar value; Bristol was successful in 17.6 percent of the dollar value; Squibb was successful in 17.5; and Upjohn, in only .5.

Three companies—Lederle, Bristol, and Squibb—have approximately 53 percent; Pfizer, 47 percent.

Do you have any explanation for that unusual occurrence?

Mr. Duncan. Mr. Dixon, could I ask why did you stop in October of 1959?

Mr. Dixon. Why did we stop in October 1959? The next purchases were, I believe, from the Italians.

Mr. Duncan. Mr. Dixon, the thing that occurs to me here, it is hard to comment on these things when they are put in front of you, and the thing that occurs to me, I can't say just when, but certainly it wasn't more than 6 months ago that our man who works in this particular field had managed to get a sirup, which is not listed here, on the list for purchase.

Now, I am sure that was a pretty substantial contract. We thought we had it, and for some reason the bid was thrown out and Squibb came in and took it on the rebid. That isn't in here, and I know that was a regular MMSA procurement.

And it was a big quantity, so it would make a difference.

Mr. Dixon. We asked them to give us—

Mr. Duncan. Mr. Dixon, there is another thing, too. Coming in here somewhere there are some rotation contracts involved.

In other words, I never saw these figures put together. I mean I believe if you put all the figures together, this coincidence that you are trying to point out here just does not occur.

Mr. Dixon. I assure you, sir, the Agency put them together. We did not put them together. This is the information on their total purchases, and this is the way it came out. This is it, Mr. Duncan.

Mr. Duncan. No, I don't think you will find that information is complete. I wish you would go back and ask them.

You see, they treat a lot of dependents of servicemen as well as servicemen themselves, so they had been using a suspension, but they always prefer a liquid because children take a liquid much better than they take a suspension, and there was a big contract that came in here—I can't recall these events—it was something like 6 months ago, that was a substantial amount. We thought we would

get it because we had our products specified, and Squibb took it.

So that certainly is not here, and I think there were two rotation contracts that came in here somewhere, so I just don't believe you have included all the items.

Senator Kefauver. We asked the Agency for this information and this is what they gave us.

Mr. Dixon. Mr. Chairman, I understand this to be the total up to the time that the Italian entrance into this market changed the situation.

Are you talking prior to that time or after that time?

Mr. Duncan. My recollection—

Mr. Hesse. The Italian was October 28, 1959, the first Italian, but it was only capsules.

Mr. Duncan. All I know is that that was at least one purchase of a very important product. That is second only to tablets in our civilian market, and that is not included here.

Mr. Dixon. We will have the MMSA before us tomorrow, and we will refer to this. But this is a long-term period, 3 years. Over this 3-year period, Pfizer received 47 percent of the business and the other three divided practically equally.

Do you have any explanation for that?

Mr. Duncan. Let me ask you another question.

Are you sure you have not picked this period—for example, you say November 1956. Does that include the first contract which we got on tetracycline?

Mr. Dixon. This, as I understand it, is from the first time the Agency bought tetracycline up to the time that the Italians entered the market, which apparently disrupted the situation. They said it was for all forms of tetracycline.

Mr. Duncan. I don't know about disrupting the situation. All I can say is I just don't think these figures are complete.

You picked a period here where the figures come out this way, but this is not the complete purchases from the time they first bought tetracycline up to the present time.

Senator Kefauver. Suppose you take this exhibit and if you can complete it tonight, if you have any figures to add, do so. In the meantime, we will ask Admiral Knickerbocker about it tomorrow. It includes the same period of time as is contained in the chart marked "Exhibit 21," from the time tetracycline was first purchased by MMSA until the Italian company come into the market.

Mr. Duncan. Senator, this is obviously a selected period and selected products, and until we have a chance to check it against our own records, I can't make any comment on it.

Mr. Dixon. Mr. Chairman, before we go, I want to make one comment.

Tetracycline is tetracycline, isn't it?

Dr. Malcolm. Yes sir. If it is a pure substance.

Mr. Dixon. And it has to be certified and passed on?

Dr. Malcolm. That is correct, sir.

Mr. Dixon. During your statement, Dr. Malcolm, you made two references. In the exhibits that you presented, for instance, on your table 5, you showed the importance of Achromycin, which, as I understand it, is your form of tetracycline; is that correct?

Dr. Malcolm. Yes.

Mr. Dixon. You showed your dollar sales there in millions of dollars. Later in your statement you pointed out your promotion expenses and you broke them down on the table after page 22 to the total amount of $3.51 per doctor per month. You said this is for 200,000 doctors, and my arithmetic says that adds up to $700,000 per month; isn't that correct?

Dr. Malcolm. Yes, I am sure that represents all Lederle products.

Mr. Dixon. That is right. But as I understood your statement, $3.51 is spent per doctor per month. Since you figure that on 200,000 doctors, that total is $700,000?

Dr. Malcolm. Yes.

Mr. Dixon. I would assume that a great deal of that promotion had to do with this important product of yours, Achromycin; isn't that correct?

Dr. Malcolm. That is correct. You select your leading items and you spend a proportionate share of advertising and promotion and detailing on your leading items.

Mr. Dixon. My point is this, sir:

You spent a great deal of money trying to convince the American doctor that your product—which is identical with four others—is superior, haven't you?

Dr. Malcolm. It is identical from the standpoint of the pure substance, but there is a great deal of processing which takes place from there on.

Mr. Dixon. But you could not sell that product unless it was certified and examined by the Food and Drug Administration?

Dr. Malcolm. That is correct.

Mr. Dixon. Nor could anyone else?

Dr. Malcolm. That is correct, but—

Mr. Dixon. And it has to meet those standards, does it not?

Dr. Malcolm. That is true, but in some instances, as I pointed out, I think, we go beyond even certification standards.

Mr. Dixon. What you are trying to say is that an identical product is still better if you make it, is that it?

Dr. Malcolm. Absolutely. Thank you, sir.

Mr. Dixon. I will say this: the Food and Drug Administration set up the standards, did they not, and if other companies met those standards, they are adequate, are they not, sir?

Dr. Malcolm. They are minimum adequate standards, yes.

Senator Kefauver. I wonder, instead of spending $700,000 a month in trying to convince doctors that your product is superior, why some of that $700,000 spent on a price reduction wouldn't have increased your sales?

Dr. Malcolm. Mr. Chairman, there are other products against which we are competing, and we even have to paddle downstream in this highly competitive industry.

And, in our opinion, the sums of money being spent in acquainting the doctor with our products is very well spent.

If you do not maintain your markets, they soon—

Senator Kefauver. $700,000 a month is $8,400,000 a year. You gave us the figure that you spent $50 million on sales—

Dr. Malcolm. That is out of $200 million total sales, Mr. Chairman. You won't find that exorbitant in terms of the fact that we have several hundred products that we are trying to sell.

Senator Kefauver. What I am asking is which of your exhibits is correct—your chart which shows you to spend $8 million a year or your table that shows that you spent $50,418,000 a year. In other words, you sent us—

Dr. Malcolm. I do not follow that.

Senator Kefauver. Selling and distribution, I take it, includes many items.

Dr. Malcolm. Are you talking about total selling expense including detailed promotion, samples, and so forth? Yes.

Senator Kefauver. For drugs, that is right.

Mr. Dixon. You were talking about them on your chart: samples, journal advertising, mail advertising, other advertising, and other promotion. So you are talking about the same thing.

(The chart referred to, exhibit 10, may be found on p. 13645.)

Dr. Malcolm. This is advertising and sales promotion. That has no reference whatever to the money spent on distribution, detailing, about 800 detail men.

Mr. Dixon. Eight hundred detail men?

Dr. Malcolm. Yes.

Senator Kefauver. I think we ought to get this straightened out. On the information you provided us in response to our subpena, you have listed samples, $5,814,000. That category is included in your chart, exhibit 10. You have direct mail, $2,600,000. That category is also in exhibit 10. You have periodicals, including journals, $5 million. You have other sales promotion, $4,433,000, and other advertising, $1,511,000. That is over $19 million right there.

Dr. Malcolm. I am not familiar with this. Is this Form 1: Comparative Income and Expense?

May I refer that to Mr. Duncan?

Mr. Duncan. I think probably the difference is this statement you are referring to, Senator, is our worldwide drug business. Now, the chart I think, Mr. Dixon, that you are referring to has to do only with our domestic advertising and sales promotion.

Senator Kefauver. I think we ought to straighten out what it does or does not say.

Is this based upon what you spend on doctors in the United States and on others in your international business?

Mr. Duncan. That is correct.

Mr. Dixon. Do you advertise only to doctors in the United States, or anywhere in the world?

Mr. Duncan. I didn't get that question.

Mr. Dixon. All of your advertising and promotion is directed to doctors wherever they are, isn't that correct?

Mr. Duncan. Yes, but the difference in those figures is that in the statement we have more details. That includes the doctors in the United States and includes only advertising and promotion expenses in the United States. This form which we submitted with the breakdown is our worldwide drug business as it states here on the second page.

Mr. Dixon. You are saying that you spent six times this amount for advertising and promotion outside the United States. Is that what you want us to believe?

* * *

First Opinion of Court of Appeals, 363 F.2d 757

Administered Prices

THURSDAY, SEPTEMBER 8, 1960

U.S. Senate
Subcommittee on Antitrust and Monopoly
of the Committee on the Judiciary,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:12 a.m., in the caucus room, Old Senate Office Building, Senator Estes Kefauver presiding.

Present: Senators Kefauver (chairman), Hart, Dirksen, and Hruska.

Also present: Paul Rand Dixon, counsel and staff directors; Horace L. Flurry, counsel; Peter N. Chumbris, counsel for the minority; Nicholas N. Kittrie, counsel for the minority; George E. Clifford, assistant counsel; Dr. John M. Blair, chief economist; Lucile B. Wendt, attorney; Dr. E. Wayles Browne, Jr., economist; Dorothy D. Goodwin, attorney; Dr. Irene Till, economist; Paul S. Green, editorial director; and Gladys E. Montier, clerk.

Senator Kefauver. The committee will come to order.

* * *

Mr. Duncan. Senator, there was one other thing left open on exhibit 22. Did you intend to refer to that, Mr. Dixon?

Mr. Dixon. Sir?

Mr. Duncan. You presented late last night, when we were all rather tired, this exhibit 22 on purchases of tetracycline.

Mr. Dixon. Yes, we did.

Mr. Duncan. And asked us for any comments, and we had a chance to check the figures last night and we wanted to comment on that exhibit.

Is this the appropriate place to do it?

Senator Kefauver. All right, sir, you may do so now. Suppose you give us the percentages that you have.

Mr. Duncan. Yes.

Now, we have—I would like for you just to look quickly at these figures. It will take only a moment. What we did was—while they are handing them out—what this chart, exhibit No. 22, showed were the Tetracycline purchases from November 1956, to October 1959.

I don't know what implications Mr. Dixon intended to read into this, but he pointed out the similarity of some of the percentage figures shown on that chart.

* * *

Mr. Dixon. Mr. Chairman, before you leave that point, I believe you stated, Mr. Duncan, that the Veterans' Administration never in the past bought in large quantities.

Mr. Duncan. That is right.

Mr. Dixon. I have before me exhibit 21, which lists bids to MMSA. In October of 1956 you bid $11 and won the award. In May of 1957 Pfizer bid $11 and won the award. Now in September of 1957 the Veterans' Administration sought 50,000 bottles. That is not a small order.

Mr. Duncan. How much did they award? You see, they always quote very large quantities to lure you into a low price.

Mr. Dixon. The total price was $880,000. That is not insignificant. The unit price secured from Pfizer on that order was $17.60. But Lederle bid $19.58.

Mr. Duncan. Was the award—the award was $880,000? If so, it is the biggest order they had ever placed.

Mr. Dixon. Then again in March 1958 on an advertised bid for $50,000, Pfizer bid a $17.24 unit cost for a $862,000 order.

Mr. Duncan. Mr. Dixon, without those figures in front of me, I cannot check all the figures and see just what you

are talking about. I am merely saying that the awards, except for maybe the one you are mentioning there, have always been small. Mostly they were merely hunting licenses, not firm contracts as they were with the MMSA.

Mr. Dixon. The observation I make, Mr. Duncan, is this: Twice MMSA was able to secure tetracycline in bottles of 100 for $11. At that time the Veterans' Administration was paying considerably more, about $19.58. The VA went to the MMSA trying to get its order grouped with the MMSA order, and the next time that MMSA came back and tried to purchase a sizable order, the price went back up from $11.

Mr. Duncan. I was never aware—

Mr. Dixon. And stayed up.

Mr. Duncan. In fact, I had always wondered why the MMSA had not been buying for the Veterans' Administration for several years. In fact, I once asked Captain Wise why that was not the case. I have never had any information to this day that they were doing that or were interested in doing that.

I raised the question because they are both Federal Government agencies and I could not understand myself why they did not get together. But I never had any information that they ever had or that the proposal had been made.

Senator Kefauver. I do not know whether we completed the patent question yesterday or not. You said when this patent matter was settled, Pfizer insisted on buying tetracycline from you in bulk. They were not manufacturing it at that time themselves.

Dr. Malcolm. No. We were the only manufacturer of tetracycline at that time.

Senator Kefauver. Do they manufacture it now?

Dr. Malcolm. Yes; they do.

Senator Kefauver. How long did you supply them theirs in bulk?

Dr. Malcolm. I do not know the exact period in term of weeks, but it was a very short period of time.

Senator Kefauver. Was that the finished product?

Dr. Malcolm. That was in bulk form.

Senator Kefauver. Ready to be tested and bottled or capsuled?

Dr. Malcolm. Ready to be tested, bottled and finished.

Senator Kefauver. What was your price to Pfizer?

Dr. Malcolm. I do not recall exactly the price, but I think it averaged out in terms of the total quantities they purchased in the neighborhood of 37 cents a gram.

Senator Kefauver. 37 cents a gram?

Dr. Malcolm. Yes.

Senator Kefauver. It might have been a little below or a little above?

Dr. Malcolm. In the beginning it might have been a little above, I do not know. But it averaged out around 37 cents a gram.

Senator Kefauver. And what was to be done afterwards? You made a good product. They tested it, bottled it, and put their label on it?

Dr. Malcolm. I presume so. After it left our hands, it was, of course, their responsibility.

Now, the period Mr. Duncan speaks of is the period after the expiration of the agreement or the disagreement between Farmitalia and Alfar and our date of acquisition, at which time Farmitalia joined the ranks of Laikti and the eight others who are now manufacturing tetracycline and trying to sell it all over the world.

Mr. Dixon. All right, sir.

Now, I want to address myself to the recently announced 15-percent price reduction of antibiotics.

Mr. Duncan, are you going to answer, or is Dr. Malcolm?

Dr. Malcolm. Mr. Duncan.

Mr. Dixon. All right.

Mr. Duncan, on or about August 1, there appeared in the press an announcement that a 15-percent price reduction was going to be made across the board on broad-spectrum antibiotics.

Will you explain to us your method of merchandising tetracycline as an example, or all of your antibiotics, to the retailer prior to this time?

Mr. Duncan. Yes.

We have a number of so-called direct accounts to whom we sell directly. We supply them from about 13 of our branches located all over the country.

These accounts consist not only of drugstores but of a number of private hospitals. We also—those are the direct accounts we handle and they are the larger and more important accounts.

We also supply our products through the wholesaler to whom we gave at that time a discount, I believe, of 16⅔ and 5 percent below the retail price.

Mr. Dixon. 16⅔ plus 5?

Mr. Duncan. We are talking tetracycline. It is easier to talk a specific product.

Mr. Dixon. Yes, sir.

That was the condition that existed prior to your change?

Mr. Duncan. Yes. I believe the prices were $30.60 to the retail trade per bottle of a hundred and the wholesale price, $24.22, or something like that.

Mr. Dixon. $24.22.

Now, what is the change that you have made?

Mr. Duncan. Pfizer was the first company that made the move. They reduced—let me take a moment—they reduced the price to direct accounts by 15 percent, and that figure, as

I remember, was around what—$26? Somewhere around that figure.

Senator Kefauver. $26.01.

Mr. Duncan. $26; that is correct.

Now, we followed that. This happened on a Saturday. They tried to steal a march on the industry, I guess. They sent out telegrams to the trade on a Saturday.

Senator Kefauver. They tried to do what?

Mr. Duncan. Steal a march on the rest of the industry, I suppose, because they did this on a Saturday.

Senator Kefauver. You mean after 10 years of operation, they should suddenly steal a march on you?

Mr. Duncan. Yes, Senator.

These things happen very rapidly. If you can get any kind of an advantage on your competitors, you try to do so.

So they confronted us, they did this, as I recall, on a Saturday morning, and the first thing I heard about it was at 8:15 on Monday morning, when my sales department was in my office practically having hysterics about meeting it immediately.

Senator Dirksen. It proves there is no competition, doesn't it?

Mr. Duncan. Yes.

Mr. Dixon. Let's keep to the subject. And you met it? Did you meet their price?

Mr. Duncan. Yes; we met it.

Mr. Dixon. Just exactly how did you meet it?

Mr. Duncan. Prior to that time, going back for a long time, we had had a so-called Lederle plan. Now, under the Lederle plan our direct accounts with whom we dealt directly, and we were happy to deal directly with anyone who could give us a substantial order a month, was to allow them an extra discount of 7½ percent, I think, on a $50 order and 15 percent on a $100 order. So what we did—now, let me say this was the case on all our products with the sole excep-

tion of our antibiotics. Now, what we did in order to meet this price immediately was to put the tetracycline on the regular Lederle plan, so that it meant that any direct account buying a $100 order would buy it at $26.01.

Mr. Dixon. He would get 15 percent off?

Mr. Duncan. Yes.

Mr. Dixon. If he bought a $100 total order?

Mr. Duncan. Yes.

Mr. Dixon. Prior to that time, if a retail pharmacist wanted to buy antibiotics or tetracycline, he had to go to the jobber to get it, is that correct?

Mr. Duncan. Or to us.

Mr. Dixon. Or to you.

Mr. Duncan. Yes.

Mr. Dixon. In the past, would you give him 15 percent off if he came straight to you?

Mr. Duncan. No, we did not have that on the Lederle plan.

Mr. Dixon. So in the past he went to the wholesaler for it?

Mr. Duncan. Actually, he did not. Specifically, the business was divided about 50-50. In other words, the wholesalers did about 50 percent of the antibiotic business and we did the other 50 percent direct.

Mr. Dixon. Let's talk about those who did go to wholesalers. If they went to the wholesaler, the wholesaler got a price of 16⅔ percent, plus 5 percent discount?

Mr. Duncan. Yes.

Mr. Dixon. Under your new plan, if the retailer comes straight to you, he will only get 15 percent?

Mr. Duncan. That is correct.

Mr. Dixon. So actually, on the business that previously passed through the wholesaler's hands and that may come straight to you from the retailer, you will come out the

winner, won't you? There is the difference between 16⅔ plus 5 and 15, is that correct?

Mr. Duncan. To that extent, yes.

Senator Kefauver. Let's see if I get this clear. You mean that whereas previously your wholesaler got 16⅔ plus 5, as his margin, and then when the retailer purchased at $30.50 from you, he purchased it at the same price from the wholesaler.

Mr. Duncan. That is correct.

Senator Kefauver. And now, you have given the retailer a 15 percent discount when he purchases it directly from you. Have you done nothing to enable the wholesaler to continue his business?

Mr. Duncan. Up to this point this is a practice which we have followed on all our other products for quite a long time, Senator. What we have done, on all the products except tetracycline for a period of several years we have had this plan in effect. What we tried to do is this: We can handle the larger accounts on a direct basis, and we do, and have been doing so on our other products for quite a long time. Now, on many of the smaller drugstores and small accounts, over the country, those are normally the accounts that the wholesaler handles. In a typical product 30 to 35 percent of the business will go through the wholesaler. He performs many functions for them. He fills out their line.

Senator Kefauver. Yes, we know that, but as to the wholesalers' situation on tetracycline, he only has left a 6⅔-percent margin in which to operate.

Mr. Duncan. Yes. Now, actually, each company's distribution plan varies very considerably.

Senator Kefauver. I am just talking about your plan. In other words, he did have a 21⅔-percent margin on which to operate. He now has only a 6⅔-percent margin because you have not given him a discount.

Mr. Duncan. In many cases you will find that the wholesaler, because he performs these other functions, charges a higher price than we do to our direct accounts. We give that only to those accounts that can buy in sufficient volume to cut the costs and enable us to do it. Now, the wholesaler habitually will sell at a higher price than we will sell direct because he performs a number of other functions.

Senator Kefauver. Aren't you going to put your wholesalers out of business?

Mr. Duncan. No; because except for tetracycline, this has been our plan of distribution for at least the last 7 years or 8 years on all our other products.

Mr. Dixon. Let us get this in dollar figures so we can understand it. Previously, you sold, and you still sell to your wholesalers, at $24.22 for a hundred?

Mr. Duncan. That is correct; we have not changed that price.

Mr. Dixon. Now, under your new plan, if you sell straight to the retailer, what will that price be per hundred, $26?

Mr. Duncan. On $100 orders, only on large orders, $26.01.

Mr. Dixon. So you are going to make practically $2 more on those orders?

Mr. Duncan. It is questionable how much of the wholesaler business we will take because we do not pretend to give all the services which a wholesaler provides. And many other companies have a one-price policy that charges the same price to the retailer and the wholesaler. Each company's distribution plan varies very considerably, and so we really are only formalizing in putting tetracycline—

Senator Kefauver. That does not answer the question. On the plan you have worked out, you were selling to the

wholesaler at $24.22, but you are now going to bypass the wholesaler. The practical effect, of course, will be that he cannot operate on a 6⅔-percent margin, selling direct to the druggist at $26.01, so that you are going to be getting $1.80 more for your product than you were before.

Mr. Duncan. Actually, the wholesaler has been operating on every other product in our line for the period of the last 7 or 8 years on this margin. As I say, for the services he performs he does not sell at $26.01. He sells at a higher price to many of these accounts, because they buy in very small quantities. He provides their inventory control. He carries their stock for them. He performs all kinds of services. As I say, really the distribution plan of one or two of the other companies is a one-price policy to wholesalers and retailers and even there the wholesaler does a very substantial amount of business.

Senator Kefauver. There must have been some good reason for your giving the wholesaler 16⅔ plus 5 for a long, long time to enable him to stay in business. You are now reducing that to where he will only get 6⅔ percent. If your reason for giving him a 21⅔ percent in the beginning was sound, why do you reduce him to 6⅔ percent now?

Mr. Duncan. This wholesale discount goes back for a long period. As I say, 7 or 8 years ago we decided that we could perform the same function as the wholesaler performs and should do so on major products, on major orders. We have not tried to do so on smaller orders. So our distribution system is simply a blend of the two things, direct sale to direct accounts, and use of the wholesaler on the hundreds of thousands of nondirect accounts.

Senator Kefauver. Why do you object to giving the wholesaler the 15-percent reduction, too?

Mr. Duncan. We do not feel it is necessary. We have been wanting to place tetracycline on the same basis as

our other products for quite a long time. This afforded a good opportunity to do so and now we have a standard policy right through the line.

Mr. Dixon. And everybody is doing the same thing?

Mr. Duncan. No; I do not think so. Look, I have been preparing for the hearing and I am not up to date, but I believe that Squibb and Bristol at least, and I do not know who else, has dropped the wholesale price from $24.20 or whatever their price was, to something less than $22. I cannot testify on this directly, Mr. Dixon, because I have not been close enough to these events and they have been happening too rapidly.

Mr. Dixon. I will read from the so-called Green Sheet called Weekly Pharmacy Reports. This appears:

> The new this week, August 29, 1960. The month-old "trade discount adjustment" on tetracycline first announced for August 1 by Pfizer, became a frank price cut on antibiotics last week when Lilly and Upjohn took the final, inevitable steps of reducing prices at all levels including the suggested price to the consumer. This is the first significant price reduction in a major area of drug therapy since the penicillin and cortisone price wars of the early and mid-1950's.

I want to ask you whether you have reduced your fair trade prices to the consumer yet.

Mr. Duncan. We have not yet.

Mr. Dixon. You have not?

Mr. Duncan. Not yet.

Mr. Dixon. So that the extra 15 percent under your present policies has to stay in the druggist's hands. He has no choice under fair trade.

Mr. Duncan. Not entirely. After all, as you well know, there is a difference between our suggested price and our fair trade price, which affords merely the floor. We do not try to dictate what druggists charge.

But the fair trade price does constitute a floor which is 10 percent below the suggested price.

Mr. Dixon. In those States that have fair trade prices, if the druggists were selling at the fair trade price, had he passed it along, he would be violating the law today under your policies; would he not?

Mr. Duncan. That is right.

Mr. Dixon. So it is not a price reduction to the consumer under your plan yet; is it?

Mr. Duncan. Not yet. The reason I say not yet is that I have been involved with other things, and haven't had a chance to follow these very fast-moving developments, and I am not prepared to say exactly what course of action we will take. But we probably will meet competition as we have always done.

Mr. Dixon. We have examined this in great detail earlier—for instance, your price to the druggist previously per hundred was $30.60.

Mr. Duncan. That is correct.

Mr. Dixon. Your suggested price to the consumer was $51.

Mr. Duncan. That is correct.

Mr. Dixon. I believe that is a 66⅔-percent markup that you suggest.

Mr. Duncan. Or a 40-percent margin as they look at it.

Mr. Dixon. They look at it backwards. In my way of thinking, if you buy something for $30 and you mark it up to that, I think that is a markup going that way.

Mr. Duncan. Well, now, that also, not to digress, is kind of a mathematical trick on the thing. We have used this markup. For example, you can look at it from the standpoint of aureomycin. We reduced it from $15 to $5 so that is a reduction of only 66 percent. In fact, if we had reduced it to $1 you couldn't reduce it 100 perecent but if you raise it from $5 to $15 that would have been a 300-

percent markup, so to some extent this markup is a mathematical trick, kind of a gimmick.

Senator Kefauver. In any event, we were all elated over the fact that for the first time in 10 years there was, we thought, a price reduction to the consumer and that you were going to sell at 15 percent less. It now develops that so far as you are concerned, you are fixing the price at $51 as the minimum price that a retailer can sell for; it is still $51.

Mr. Duncan. $45.90, Senator. The floor is 10 percent under the suggested price so the floor, I think, is $45.90.

Senator Kefauver. Anyway you have not changed the floor.

Mr. Duncan. We have not changed the floor as yet.

Senator Kefauver. So that even if the retailer in a fair trade State wanted to pass on this 15 percent to the customer, he could not do so under your plan.

Mr. Duncan. As of this morning. As I say, this is under serious study. We have had these fast-moving developments, and in the past we have always met this competition. I haven't had the time to give it the thought or even to catch up and find out factually exactly what has happened, because the distribution of our competing companies, their distribution systems vary and it is hard to get the details.

Mr. Dixon. Mr. Chairman, on that point, in this same issue of the green sheet that I read from, this appears:

> Upjohn's tetracycline fair trade minimum revised downward. Upjohn followed through with a letter to retail pharmacists announcing "comparable percentage reduction in the minimum resale price" of its tetracycline products on which it had previously reduced the net price to retailers. "Price adjustments," Upjohn told its retail pharmacy customers, "on packages purchased prior to August 9, 1960, and in your

> inventory on August 20, 1960, will be allowed when reported to our salesmen together with the invoice date. Bristol Labs * * * had earlier brought its price structure into line. It affected a 15-percent price cut by establishing a schedule of net prices. Pfizer, Lederle, and Squibb are still confronted with the question of frankly admitting that their earlier actions on tetracycline have now become plain price cuts across the board. To do this, they have to adjust downward their suggested retail-to-consumer prices which form the base against which their trade discounts are computed.

And so on.

Dr. Malcolm. Mr. Chairman, I don't think that you can ask us to make a price decision, here, can you? It is a matter under very serious discussion among us, and it is something that we will have to deal with after we get back home.

Senator Kefauver. We are not asking you to make any price decision here. This happened on August 1. It is now September 8.

Dr. Malcolm. Not August 1.

Senator Kefauver. Excuse me, this happened on July 31, effective August 1.

Mr. Duncan. Not the price to the retailer, Senator. This has been a very mixed and muddled situation with a succession of moves.

Senator Kefauver. I have here Pfizer's telegram to one of the pharmacists dated July 30, reducing the price 15 percent.

Mr. Duncan. To the retail trade only, and we met that immediately.

Senator Kefauver. Yes, and here is your telegram of August 3.

Mr. Duncan. That is right.

Senator Kefauver. In which you do the same thing. So this has been in effect over a month, and you haven't done anything about it.

Mr. Duncan. This has only been just moving down the retail trade price. That is all we did.

Senator Kefauver. And you haven't done anything about allowing wholesalers any adjustments?

Mr. Duncan. Not to this point. We have simply got our tetracycline in line with all our other products.

Senator Kefauver. Assuming that the wholesaler can't operate on a 6⅔-percent markup, and I don't think he can, because he has to keep a large stock—

Dr. Malcolm. Of course. They have been doing it.

Senator Kefauver. They are going to be put out of business insofar as tetracycline is concerned. The net result will then be that you will be selling the product at a higher price actually than you were before.

* * *

Mr. Dixon. You fair-trade your products, do you not?

Mr. Duncan. Yes, we do at the retail level only, not the wholesale.

Mr. Dixon. Who sets that retail fair-trade price?

Mr. Duncan. We do.

Mr. Dixon. You do it independently?

Mr. Duncan. We certainly do, yes.

Mr. Dixon. You do not take the druggist into your confidence? You do not talk to them, about what they desire? You do it, is that it?

Mr. Duncan. We do it, yes.

Senator Kefauver. Let me ask this: I have always wondered—

Dr. Malcolm. There are 28,000 druggists.

Senator Kefauver. The druggist is entitled to make a reasonable profit. You do not talk about his business with

him, so how can you fix a minimum fair-trade price? How can you know that the druggist is going to come out all right, that he will make a fair amount of money? How can you know that the position of the consumer is going to be protected? I do not see how you just arrive at these fair-trade prices in a vacuum without considering the consumer, without considering the druggists, or without talking it over with them.

Mr. Duncan. As we said yesterday, we set our competitive prices and the prices we charge are the prices to the retail trade, the so-called net trade price. Now we have to set that, as we pointed out yesterday, with a great many things in mind, and I won't go through it again, but competition is a very important factor, and a lot of the other things, the money we have to invest in plant facilities, obsolescence and so forth. Now as you well know, there is —over the years there has grown up an established practice of allowing the druggist to mark it up over our price, as Mr. Dixon has said, 66⅔, or to operate at a margin of 40 percent. So that simply follows logically from the price which we set on the basis of all the factors we have talked about.

Mr. Dixon. If you will examine exhibit 18, which we put in the record yesterday, you will note that the suggested resale prices to consumers of tetracycline, Aureomycin and Terramycin in any solution form that you can think of are identical as among the different manufacturers. How does that come about?

Mr. Duncan. I can only answer your question on the capsules which are the leading product that I know about, and on the others so far as I know, if they are identical products competition is going to keep the price the same.

Mr. Dixon. Do you call it competition when you set the fair-trade price?

Mr. Duncan. I really am setting a price to the druggist in the hospital. Naturally, the net trade price follows routinely from whatever price we set.

Mr. Dixon. Yes, but my point is this: The druggist cannot sell below that price.

Mr. Duncan. That is correct.

Mr. Dixon. In fair trade.

Mr. Duncan. In fair trade States.

Mr. Dixon. And you set it. You set the minimum level to which he must adhere or he violates the law. You set the price.

Mr. Duncan. We do not set the price. We set a floor. All we are saying is that we suggest a price 66⅔ percent above our net trade price. We suggest that price. That has been a practice for a long time. We then set a net trade price as a floor, 10 percent below that. The druggist charges anything he feels he needs to charge because the circumstances will vary.

Mr. Dixon. Above your floor.

Mr. Duncan. Above the fair-trade price. That is the floor.

Mr. Dixon. And your floor on 100 tablets was $49.90.

Mr. Duncan. $45.90 for our capsules; 10 percent under.

Mr. Dixon. And 10 percent is added to that. Now we note all other sellers set the same floor.

Mr. Duncan. I would assume that it would follow if we were competing and the price were the same, the net trade price were the same to the retail druggist, then I won't pretend to speak for what the others did or how they intended to do it, but so far as we were concerned, we followed the same practice we follow on every other one of our products.

Mr. Dixon. Yesterday, Dr. Malcolm, when he was making his statement, put in the record and exhibit which we marked as "Exhibit 9." It purports to represent the dis-

tribution of the consumer's dollar paid for Lederle drugs in 1958. You took the dollar and you said the manufacturer received 51 cents, and the retailer and wholesaler received 49 cents. That was figured on your suggested sale price to the consumers.

Mr. Duncan. Yes, that is correct.

Mr. Dixon. So really you are the one who is fixing the consumer price, then, are you not?

Mr. Duncan. No, no, we are setting a floor. We are simply setting a floor on the basis of net trade, and the retail druggist sets the price. The price varies in many cities.

Mr. Dixon. Let's talk about the floor, then, $45.90. It is you who is determining as a matter of law in fair-trade States what the consumer must pay regardless of how that dollar that he spends is split up, the minimum amount that he must spend, isn't that correct?

Mr. Duncan. Yes, in the fair trade States. That is what the fair trade law is.

Mr. Dixon. Many people in the country think the druggists are responsible for this, but you are responsible for it because you are the ones who are setting that price.

Dr. Malcolm. The fair trade law is responsible for it.

Mr. Dixon. You do not have to follow fair trade. You choose to do it. It is not imposed upon you.

Mr. Duncan. We choose to do it for a very good reason.

Dr. Malcolm. We choose to do it in States where it is legal because we believe in fair trade.

Mr. Duncan. We do not want to go into it in detail, but we feel it protects the small druggist and believe me, the opportunities for a small businessman are getting more and more limited and we are strongly in favor of fair trade.

Senator Dirksen. Mr. Duncan, before we get too far afield, I want to refer to the chairman's observation as to whether you confer with the druggist before setting prices.

I was afraid you might "shoot from the hip" by way of an answer, because if you did confer, the chance are we would have you in here before this committee or some other committee on the grounds of collusion in setting prices.

Mr. Dixon. That is for sure if he agreed to do this, he certainly would be, sir. I agree with you.

Senator Kefauver. It is difficult to understand what the requirements of a drugstore are, unless there is some information that you get from somewhere. I think you would have to know what they are paying their pharmacists, what their rents are. I do not know how you would get that unless you talked either with them or with somebody who had information about those matters. Otherwise, you are just shooting in the dark.

Mr. Duncan. To my knowledge, this 40-percent margin which the druggist had, it goes back long before my time as a regular established practice.

Mr. Dixon. Mr. Duncan, let's examine this from the other end. I had a call from a small druggist who said, in effect, "I will not be able to predict the peak periods when antibiotics should be on my shelf in great quantities, and for me to take advantage of the 15-percent reduction, I not only would have to buy a particular antibiotic but I would have to buy all antibiotics," and he said, "I would have to seek a small business loan in order to buy stock." He said therefore in the instance of the manufacturer who has lowered the suggested price to the consumer, already lowered it by the 15 percent coming the other way, "I am going to find myself in the position of having to buy from the jobber." And he said, "Therefore, when I buy from the jobber, I am not going to be able to sell for $51 a hundred any more. I am going to have to sell for the new price which will have been established." He said, "I won't get the 15 percent. I will have to go back to the jobber and therefore, I won't have that advantage, but my ultimate

price to the consumer will come down." Do you have any comment on that?

Mr. Duncan. If he will buy $100 worth, we will be glad to give him 15 percent.

Mr. Dixon. He understands that, but he says he has to buy $100 from everybody and he has to keep that material there and have it in enough quantity to be able to meet the consumer demand.

Mr. Duncan. Yes. Of course, all these plans vary. That is not the case in the case of Pfizer, I believe; from their announcement in the telegram that the Senator read, it indicated at least if he even bought one bottle from them, he would get the 15 percent.

Senator Kefauver. No. The Pfizer telegram says:

Orders containing minimum $100 Pfizer Laboratories broad spectrums placed by August 26 will carry dating effective November 1.

Mr. Duncan. But wasn't that a special dating provision? Isn't it true, Mr. Dixon, as far as buying is concerned, he got the 15 percent on one bottle? I think that was a special, also a special inducement they were offering for a limited period. You see there, all these plans differ.

Senator Kefauver. All right, sir.

Mr. Dixon. Mr. Duncan, on this point of selling to Government agencies as well as to retailers, we understand that you are in competition with your own wholesaler. Based upon evidence that we have had called to our attention, isn't it a fact that you have disciplined wholesalers who in the past cut the price of your products?

Dr. Malcolm. Never.

Mr. Duncan. I don't remember of any instance, and certainly not since fair trade was knocked out to wholesalers.

Mr. Dixon. Let me try to call some of them to your attention. We understand, based upon an exhibit in the

Federal Trade Commission case, that you withdrew an additional 5-percent discount, which you normally granted to all wholesalers, from the Hale Justis Drug Co., Cincinnati, Ohio. That is exhibit 624 in that record. This discount withdrawal was made by you because during August 1954 the Hale Justis Co. bid a lower price to the city of Cincinnati on Roerig-Pfizer tetracycline products than on Cyanamid products. This is exhibit 926. We understood that this discount was withheld for a period of about 8 months and that eventually you restored this 5 percent discount to this wholesaler during May 1955 because Hale Justis had been most cooperative including—and I quote from that exhibit—

on all bid requests information from our office concerning correct prices and discounts to allow.

We also understood that you publicized this incident to all your regional managers by exhibit 820, and that this was done, I suppose, to make all these managers aware of this so they could spread the word. I don't know whether that is true or not.

Now Brown & Price on a bid that called for either aureomycin or terramycin—

Dr. Malcolm. Mr. Chairman, if I may interrupt, this is information that is now before the Federal Trade Commission, and we are not prepared here to comment on these matters in detail. I don't think it is even fair to do so. So if you want some memorandum submitted on this, we will attempt to do it for you.

(A memorandum subsequently submitted may be found on p. 16487.)

Mr. Dixon. I don't see that this has anything to do with the Federal Trade Commission.

Dr. Malcolm. It is before the Federal Trade Commission.

Mr. Dixon. You are before the Subcommittee on Antitrust and Monopoly of the Senate *on the same subject matter.* (Emphasis supplied.)

Dr. Malcolm. We are not prepared to submit material.

Senator Kefauver. The thing is, we have been talking about wholesalers, and from this record, and I have looked at part of it, it would seem that some of your wholesalers may in some cases have sold at a lower price to the druggist or to hospitals than you would sell, and that you have taken action to chastise them and cut off part of their account, to reprimand them, and that you have passed word on to all of your sales representatives about what you had done in order to try and get them back in line. Is that a policy you follow?

Senator Dirksen. Mr. Chairman, before Dr. Malcolm answers, I think this committee had better remember that the Federal Trade Commission does have authority to issue cease and desist orders and that is punitive in character. I do not believe you should be called upon to respond to any line of inquiry that in your judgment may prejudice the case before a regulatory agency of Government that is equipped with that power.

Dr. Malcolm. Thank you, sir.

Mr. Dixon. Senator Dirksen, if you will excuse me for the comment, the Federal Trade Commission does not have punitive power. It only has the power of injunction. It can say, "Stop what you have been doing."

Senator Dirksen. If that isn't punitive, I don't know what is.

Mr. Dixon. Punitive in the law, I believe—

Senator Kefauver. It has no right to issue a fine or mete out any punishment.

Dr. Malcolm. We are prepared to submit a written statement. We are not prepared now to comment on the

allegations that you make. Certainly I am not familiar with them. Are you familiar with them?

Mr. Duncan. It goes back before my time.

Dr. Malcolm. So I think it is unfair to ask us to do so.

Senator Kefauver. I will tell you what we will do, then. We will give you the citations from your memorandum of instructions sent out to your wholesalers, and to your representatives about how to deal with your wholesalers, and ask you for your comment.

Dr. Malcolm. Thank you very much, sir.

Mr. Dixon. Mr. Chairman, I now want to take up the question of foreign prices.

I believe, Dr. Malcolm, that chlortetracycline was the first of the broad-spectrum antibiotics introduced. That was in 1948.

Dr. Malcolm. That is correct.

Mr. Dixon. I believe it was sold under the trade name of Aureomycin throughout the world, also; is that correct?

Dr. Malcolm. That is correct.

Mr. Dixon. How many companies have you licensed to manufacture or sell Aureomycin?

Dr. Malcolm. Throughout the world?

Mr. Dixon. Yes, sir.

Dr. Malcolm. I do not have those figures. I do not have that information at all.

Mr. Hesse, who is general manager of our international division, tells me that he has, so perhaps we can save time by referring the question to him.

Mr. Dixon. Let me read them to him and see if this is a correct list.

You have licensed Rhone-Poulenc of France, Alfar of Italy, Chemie Grunenthal of West Germany, RIT of Belgium, Pharmaceutical Industries, Inc., of the Philippines, Laboratorios Reunidos of Spain, Interchemie of Austria, and Biochemie Gesellschaft in Austria. In addition, I believe that a number of your subsidiaries abroad have

received licenses for sale in specified territories; isn't that correct?

Mr. Hesse. Also for fermentation.

* * *

Mr. Dixon. Some of it. And the other material is taken from public documents. So it is something that is in the public domain right now. I think that my answer to Senator Hruska could be that I do not think we are going to violate anyone's request for confidentiality. As to the basis for what Dr. Blair is going to explain here, as the chairman has described previously, a great deal of it came from the form 1 material, others came from information that is in the public domain, and in public documents now.

Mr. Clark. Would there be any objection, Mr. Chairman, if Mr. Dixon told us what the other public documents were, just so there would be no difference of opinion as to whether they are public or not?

Mr. Dixon. I think Dr. Blair will describe those sources. I would hope you would take my word. I am not double-talking.

Dr. Bowman. Well, as a matter of definition, would you class an in camera document as a public document?

Mr. Dixon. I am not talking about an in camera document, sir. There are in the present proceeding before the Federal Trade Commission many documents that are in the public record now that are not in camera. We may very well rely upon some of that information in what you are going to hear.

Mr. Clark. Then I would like to make another objection, based not so much on confidentiality, but on fairplay, and justice, and I think sound legal grounds, that this committee should not enter into its record, or attempt to retry here, any portion of that Federal Trade Commission proceedings. That was a backbreaking proceeding. We had 11,400-some-odd pages of testimony, hundreds of exhibits, thousands of pages, over 60 witnesses, and I think it is

highly irregular and improper to take a few of those documents and put them into this record here. We are really damned if we do and damned if we don't. We are not in a position to try to put in here all the evidence we put in there, which might be relevant, and rebut any inferences anybody might choose to draw from these exhibits.

We do not obviously want to be in a position of sitting here mute; if evidence that was adverse to us in that proceeding comes in here, we do not want to be in the position of trying to influence the hearing examiner who is deciding that case by taking positions here, retrying the issue here, and I just do not think that it is fair.

We have had a backbreaking proceeding there. We are still writing the brief on it. I should be back in my office doing that right now.

To be confronted with that evidence here, portions of that evidence here, not the complete record—I just don't think that is fair.

Senator Kefauver. For your information, Mr. Clark, this memorandum was written before we even asked for any documents for which you claimed any confidentiality.

As to our observation about the Federal Trade Commission and the fact that there is a trial going on or some matter has been submitted to the Federal Trade Commission in connection with the patent and whatnot, I have pointed out here before that this is a legislative committee trying to find out what has happened in the matter of concentration and monopoly, whether the laws are adequate, what public policies are involved and whether patent positions or monopoly positions are being used to bring about unreasonably high prices, whether patent laws should be changed, or whether the Buy-American Act should be changed.

If we had to wait for the conclusion of every issue and investigation that is now pending before grand juries, the

Federal Trade Commission or in the courts, we would just have to close up and go home. In practically every major line of industry—aluminum, cement, steel, electrical equipment, drugs, oil—there are either investigations going on or grand jury operations going on or matters are before the Federal Trade Commission.

Therefore, we would just go out of business if we had to wait until all of those are determined. We would have to legislate in a complete vacuum.

We are not trying to, and we shall not endeavor to, try any cases that are before any court or before the Federal Trade Commission, but I do think it is necessary that we get the facts upon which we can make determinations which are within the jurisdiction of this committee, and in which the Congress is interested.

I might say further that the only way that we can legislate is to have some record that everybody can read, the other Senators, the other Members of Congress, and the public, so that public opinion can be formed, so that Senators and Congressmen can make up their minds.

With just six or seven members of this committee having information which we could not impart to somebody else, it would not do the legislative process very much good.

* * *

Senator Kefauver. What do you pay a royalty to Cyanamid for?

Dr. Bowman. The Aureomycin patent, fermentation.

Senator Kefauver. This deals only with tetracycline.

Dr. Bowman. Well, the fermentation process—we do pay royalty on the tetracycline that we ferment.

Mr. Dixon. You are paying a process royalty?

Dr. Bowman. That is right. It is a process.

Mr. Dixon. You are paying a product royalty to Pfizer and a process royalty to American Cyanamid?

Dr. Bowman. That is correct.

* * *

Mr. Dixon. Mr. Chairman, before you leave that point, I understood you to say your net price on the Government bids for tetracycline—is that correct?

Dr. Bowman. I did not say anything about Government bids. I said at the ordinary levels of wholesale trade here. We have a price to Federal hospitals, institutions, and agencies, such as VA, and that sort of thing.

Senator Kefauver. You have not reduced the price to them.

Dr. Bowman. Yes.

Mr. Weeden. In that case, our price was substantially below our wholesale price, and we had no change in that particular item which was being sold under contract.

Mr. Dixon. Not the private hospitals.

Mr. Weeden. The private hospital prices were reduced.

Senator Kefauver. But I see here that your old price to the Government was $17.60, which you and the others seem to have been bidding for some time, and you continue to have a price of $17.60 for the Government; is that correct?

Mr. Weeden. That is correct.

Mr. Dixon. They did not get any bid for $17.60 anywhere to MMSA, if that is what you are talking about. There is not a $17.60 bid on exhibit 21. On tablets, at least.

Mr. Weeden. Sir, on the MMSA they submit request for formal quotations. The other Government agencies, individual installations, and so on, buy in single bottles—veterans hospitals, and so on. And there we have a regular catalog price, filed with the agency.

Mr. Dixon. But we were not talking about MMSA. We were talking about governmental hospitals, such as VA, or State hospitals, or those in that class.

Mr. Weeden. Yes, sir.

Senator Kefauver. All right.

Mr. Dixon. Mr. Chairman, before we recessed, commenting on the chart that Dr. Blair offered, exhibit 69, I made the statement that I thought his figures were conservative. That statement was predicated upon the documents which we subpoenaed from Bristol Laboratories. I have selected four of those documents. One of those documents, dated April 24, 1957, is from Morris S. Weeden to members of the management committee. The second document, dated May 7, 1957, is from E. C. Zimmerman to M. S. Weeden. A third document is dated May 17, 1955, from M. S. Weeden to Mr. Bowman. The fourth document, of December 26, 1957, is from C. H. Potter to a group listed below: Anderson, Ellefson, Harrell, Hallett, Reeve, Todt, Weeden, and White.

Mr. Chairman, I suggest that these four documents be assigned the exhibit numbers 70, 71, 72 and 73.

Mr. Bowman. Just a minute, before we assign numbers here.

Mr. Dixon. May I make just this further statement about these documents. These documents, Mr. Chairman, disclose the actual costs for a bottle of 100 250-milligram capsules of Tetrex, manufactured by Bristol Laboratories. They also show the amount of profits on a bottle of capsules of this size at the druggist's price level and the profit at the wholesale level.

These documents also disclose the cost of Tetrex pediatric drops, which is, I understand, one of the trade names for tetracycline. They also disclose the cost of the ingredient tetracycline base as well as other costs.

Senator Kefauver. Tetrex, as I understand it, is your trade name for tetracycline?

Dr. Bowman. Tetracycline is the generic name.

Senator Kefauver. Yes.

Mr. Dixon. The third document that I have, Mr. Chairman, shows the price per kilogram of sales at all levels by Bristol Laboratories, or an estimate by Bristol Laboratories of those sales.

The fourth document is the unit cost comparison for the month of November 1957 which discloses the average unit cost for a variety of tetracycline products.

* * *

Mr. Dixon. Are you through, sir?

Mr. Clark. No, I was waiting.

Senator Kefauver. We are listening.

Mr. Clark. Thank you, sir.

The hearing examiner in the Federal Trade Commission has ruled, I think correctly, that you can't prove very much by fragmentary costs—you need total costs. And in that proceeding, we had Price Waterhouse, a well-known accounting firm, make a special cost study, of all the costs that go into these tetracycline products, line by line and bottle size by bottle size, and we offered that to this subcommittee, and we offered it also in the Federal Trade Commission proceeding. And the hearing examiner ruled there that that was a satisfactory substitute for our entire raw records, you might say, showing fragmentary costs.

Now, I think those items, sir, constitute, if you will, new evidence, why it would be greatly prejudicial to us, to put in these fragmentary cost records, which can't help but prejudice the company here, heaven knows what it may do in the public eye and in the eye of the hearing examiner, when we have offered to you, and it is still available, and I would like to offer it to you now again, the complete cost study made by Price Waterhouse Co. on these products.

Dr. Bowman. I might say that this cost study was for the period from 1954 to—through 1957. It was a special study. It is not the normal type of record that we keep in the course of our business. But it was prepared according to sound and good accounting principles, and it covers all our sales of products under our own label, in the United States, for those years, giving not only the sales themselves, by unit and by total—the direct costs, the allocated costs, the total costs, and the net profit for every product we sold under our label from the years 1954 to 1957. And we are prepared to make this available. Normally we would consider this information confidential.

Senator Hruska. Is that in camera in the Federal Trade Commission?

Dr. Bowman. No, it is not, because the Government, as part of their case, did not seem to want these costs. They did not prove their point. And they did not accept it—even after the hearing examiner ruled that this was a proper substitute for the fragmentary costs that they were trying to use. They appealed that decision to the full Commission. The full Commission upheld the trial examiner. But the Government did not want this as part of their case, because this shows the full, complete picture. And we would like to offer it. I am sure you want the full picture as part of your proceedings.

Senator Kefauver. You want to offer this as an exhibit?

Dr. Bowman. We would like to offer this as an exhibit.

Senator Hruska. In lieu of what you had offered before?

Dr. Bowman. Yes.

Mr. Dixon. Mr. Chairman—

Dr. Bowman. This is in lieu of the in-camera documents which they are trying to introduce here. We wish to offer this in lieu of it.

Mr. Dixon. Mr. Chairman—

Dr. Bowman. In lieu of them. And I mean all the in-camera documents, not just the four or five mentioned.

Mr. Dixon. Before you get to that, some very serious charges have been made by you, Mr. Clark. I personally resent them. You have inferred, in fact you have said, that on the staff of this committee is an employee who worked in the preparation of this case against you in the Federal Trade Commision. You are in error. An employee on the staff of this committee, Mrs. Wendt, worked upon the antibiotics report that preceded any case by a great length of time. So you are in error there.

Mr. Clark. I apologize if I am in error. I was so informed by an attorney at the Federal Trade Commission.

Mr. Dixon. So many things are misunderstood by people not knowing what they are saying, and you just did it. You said or inferred directly—and if you are correct, we should be seriously reprimanded—that in some mysterious way employees on the staff seem to have access to material that apparently is in camera at the Federal Trade Commission. I say to you that you are in error again. I use as an example the one you used. You said there is an identical document in yesterday's record that was submitted in that case. Admiral Knickerbocker and Commander Weiss informed us that they had observed this curious phenomenon. I asked them would they prepare a document for us. If it is identical with the one at the Federal Trade Commission, so be it. But it was prepared by the MMSA at my request.

You have also inferred that these documents that I have offered here are fragmentary. I do not know what prompted the Commission's counsel to make the decision they made. I personally have not talked to them. I do not care what prompted them. All I say to you is that

Mr. Weeden prepared these documents in response to a request for costs. He did not call them fragmentary, he did not call them complete. He said, "This is our cost." And in these documents that we are talking about, in answer to a request for "How much profit are you going to make" he replied, "This is how much profit we are going to make."

I don't know what Price Waterhouse has done for you. I don't know to what documents they were given access. But if you will give us access to your books and records, we will send people there, and we will determine your costs—if you want to take us up on that offer. Give us the same acces that you gave Price Waterhouse, and we will get the truth. That is what we are after here—not fragments—but the truth. You have inferred we are playing with fragments, you have inferred that we have some kind of secret liaison with somebody who is trying your case, which is far from the truth.

Mr. Clark. All I am saying, sir, is that the proceedings that are going on here bear a remarkable resemblance to the proceedings that went on there. And I do not think we should have to fight this battle twice. At least not twice at the same time.

Senator Kefauver. Let us get this matter in perspective.

In the first place, Mrs. Wendt has been for many years an employee of the Patent Office. She was asked to come on a loan basis to the Federal Trade Commission, and help with a report on antibiotics. Her assistance on that report had nothing to do and no connection whatsoever with any case that you were involved in.

Mr. Clark. I am glad to be corrected, sir.

Senator Kefauver. No employee of this committee has been involved in that case.

While some members of the staff have formerly been employed by the Federal Trade Commission, their connection has been entirely severed, and none of them has ever had any connection with any case that you have been involved in. None of them has any method of establishing any liaison, or of getting files. We do not operate that way.

What we have secured here has been received by subpoena from your company. We have been given nothing by the Federal Trade Commission.

Mr. Dixon. Bristol Laboratories is one of the three manufacturers of tetracycline in the United States; isn't that correct, sir?

Dr. Bowman. That is correct.

Mr. Dixon. There are a total of five, as we learned the other day, that sell this drug.

You sell tetracycline in bulk form, and in some preparations, I understand, finished form, do you not, to Squibb and Upjohn?

Dr. Bowman. That is correct.

Mr. Dixon. In your statement, as I told you this morning, when you were recruiting the difficulties of your company, I believe you recited the fact that through your research program you were ever striving to develop a new antibiotic product. You said that you did develop one, and that you found out about the same time that others had developed one; is that correct?

Dr. Bowman. That is correct.

* * *

Mr. Dixon. Mr. Chairman, on that point, in examining some of the exhibits in the case before the Federal Trade Commission, I found Commission exhibit 942 which came from Upjohn's file. It is a report that concerned a meeting with Donald Gilmore of Upjohn. This is dated September 20, 1954.

Dr. Bowman. Do you have any extra copies of that, by any chance?

Mr. Dixon. I have none, but after I read it, I will send it over to you. I am reading from the third page.

Bristol is a raw material supplier making tetracycline at the present time, and not long ago Pfizer offered to settle the contest with Bristol if Bristol would sell only one customer and that customer to be Parke, Davis. Bristol said they had decided to sell two customers and one of them was to be E. R. Squibb & Sons, but Bristol would offer to sell Parke, Davis as the second, in hopes that Pfizer would settle for those two.

Bristol made a deal with Squibb and was turned down by Parke, Davis on account of the price of the material. We were next on Bristol's list.

Do you care to make a comment on that?

Mr. Clark. Mr. Chairman—

Mr. Dixon. It says on the next page:

> They offered to sell us and we accepted last week the same as Squibb did about a month ago.

Mr. Clark. I hate to keep objecting on the same ground, but this document, as Mr. Dixon says, is indeed an exhibit in the Federal Trade Commission case. Mr. Gilmore, who is purported to be quoted there testified about it. A lot of other people testified about it. There must be a thousand pages of testimony on that subject.

Mr. Dixon. But the chairman was interrogating Dr. Bowman on how it had come about that there was just two customers to whom he was selling. He was stating that he could sell to anybody else. This statement here is directly contrary to it. I think you ought to comment on it.

Mr. Clark. Well, it puts us really in a most difficult position.

I think the license agreement which was entered into 2 years almost after what you read speaks for itself as to

whether it is or is not limited or unlimited, and it frankly seems to me unfair to ask us to comment on some little excerpt from thousands of pages in a record in the other proceeding.

Senator Kefauver. Mr. Clark, it certainly is not unfair to ask you about it because it is a very important matter whether four or five companies got together and worked this matter out. That is a matter of congressional importance in connection with whether there is the rigidity of prices or whether the antitrust laws need to be amended. Your statement is that there wasn't any such agreement, as Dr. Bowman has said. Why, then, that is the end of it so far as we are concerned.

Mr. Clark. All right, sir. I have no objection to going that far, but we open up one question and then they seem to follow one another like sausages and it is hard to know when to ask you to put a stop to them.

Mr. Dixon. The sausage was apparent, sir. He had answered differently from this question that I have read. He had put the matter in issue. He said there was no such agreement and here is a statement that says there was. Now, is that statement right, Dr. Bowman?

Dr. Bowman. I did not make that statement. In fact, it is hearsay as far as I was concerned.

Mr. Dixon. Is it a true statement as far as you know?

Dr. Bowman. No.

Mr. Dixon. All right. You made your statement.

Senator Kefauver. Is the license agreement a part of the record?

Mr. Dixon. It is not a part of our record, Mr. Chairman, because we can take notice of a public document before the Federal Trade Commission. But if you want to put the domestic license agreement in this record we can do it. It may well be that we will put in the record all the license agreements, because we have been talking about them.

Senator Kefauver. I think the license agreement with Upjohn, Squibb, and Pfizer would be of interest.

Mr. Dixon. I have here all of the domestic license agreements dealing with tetracycline. I would suggest, sir, that they be given one number, and that number be No. 72 with subdesignations A, B, C, and so forth.

Senator Kefauver. If there is no objection, that will be done.

APPENDIX F

SUITS INSTITUTED BY PFIZER FOR INFRINGEMENT OF TETRACYCLINE U. S. PATENT NO. 2,699,054 AS REPORTED IN OFFICIAL GAZETTE OF U. S. PATENT OFFICE

Defendant	Filed	Court	Civil Action No.
Olin Mathieson Corp.	1/11/55	ND Ga.	5082
The Upjohn Co.	1/11/55	ND Ga.	5083
Bristol Laboratories, Inc.	1/11/55	ND Ga.	5084
Mondial Chemical Co., et al.	10/25/60	D. N.J.	927-60
Noramco	2/ 8/61	WD Tex.	2929
Philipp Bauer Co., Inc.	4/13/61	SD N.Y.	61/1320
Int'l Rectifier Corp., et al.	10/ 2/62	SD Cal.	62/1350 CC
Int'l Drug Trading, Inc., et al.	8/28/63	ED Mich.	24280
Premo Pharmaceutical Labs, Inc.	9/20/63	D. N.J.	766-33
TMCO Pharmaceuticals, Inc.	9/30/63	ED Mo.	63C-364
Narco Drug Co., Inc.	9/30/63	ED Mo.	63C-363
Hallmark Labs, Inc.	11/12/63	ND Ill.	63C-2026
Zenith Labs, Inc., et al.	11/12/63	D. N.J.	936-63
Approved Pharma. Corp.	11/12/63	ND N.Y.	9832
Davis-Edwards Pharmacal Corp.	11/13/63	SD N.Y.	63 C 3327
Pennex Products Co.	11/14/63	WD Pa.	63-1011
West-Ward Inc.	12/12/63	SD N.Y.	63 C 3619
Pennex Products Co.	1/23/64	SD N.Y.	64 C 233
Vitamix Pharmaceuticals, Inc.	2/19/64	ED Pa.	35119
Hance Bros. & White Co.	3/11/64	ED Pa.	35120
Columbia Pharmaceutical Corp.	3/11/64	ED N.Y.	64C-258
Barry Martin Pharma., Inc.	3/19/64	SD Fla.	64-175 Civ-EC
Delta Drug Corp., et al.	3/25/64	MD Fla.	64-71-J
Ortega Pharmaceutical Co., Inc.	3/25/64	MD Fla.	64-72-J
Garden Labs, Inc.	4/13/64	D. N.J.	341-64
City of New York, N. Y.	6/ 4/64	SD N.Y.	64 Civ. 1742
Freedman Pharmacy	6/26/64	ED Pa.	36060
Stoneham Lab, et al.	7/16/64	ED N.Y.	64C-752
McKesson & Robbins, Inc.	8/11/64	D. Conn.	10,600
Evsco Pharma. Corp.	1/11/65	ED N.Y.	65C-18
Diamond Labs., Inc.	3/29/65	SD Iowa	6-1652-C-2
Biocraft Labs., Inc.	3/29/65	D. N.J.	323-65
Bates Labs., Inc.	3/29/65	ND Ill.	65C-486
Henry Schein	5/ 5/65	ED N.Y.	65C-475
Wolins Pharmacal Corp.	6/ 1/65	ED N.Y.	65C-543
Mike Berk Associates	6/ 1/65	SD Cal.	65-810 EC

Public notice of the above litigation appears in the Official Gazette of the United States Patent Office, under the authority of 35 U.S.C. § 11:

692 O.G. 534; 761 O.G. 289; 765 O.G. 313; 767 O.G. 292; 784 O.G. 1142; 798 O.G. 9; 799 O.G. 8; 799 O.G. 393; 800 O.G. 630; 802 O.G. 325; 806 O.G. 956; 815 O.G. 1657.

APPENDIX G

For example, the hearing examiner made findings of fact that both Lidoff and the parties knew "that aureomycin fermentations inherently produced tetracycline;" that "Pfizer did not withhold or misrepresent any information concerning inherent production;" and that none of the three parties to the Patent Office proceedings, Pfizer, Cyanamid or Bristol, made any misrepresentations to the Patent Officer "concerning the fact that aureomycin fermentations usually contained some percentage of tetracycline." The hearing examiner further found that:

> "The various patent applications for tetracycline by fermentation, namely, Minieri, Martin-Bohonos, and Heinemann, all revealed that in the fermentation of *S. aureofaciens*, both Aureomycin and tetracycline were produced in the broth and substantial quantities of tetracycline were produced when the chlorine content of the media was eliminated or kept to a minimum. It must be noted that there is an important distinction between the presence or production of tetracycline in the fermentation broth and the presence of tetracycline in the resultant product. The Minieri application described a process which resulted in the production of substantial quantities of tetracycline in the broth, making possible the recovery of the therapeutic product, tetracycline, from such broth. The discovery of the fact that tetracycline could be produced by fermentations of *S. aureofaciens* led inevitably to the discovery that *S. aureofaciens* fermentations to produce Aureomycin necessarily produced some tetracycline in the broth, the amount depending upon the chlorine content of the media. Inasmuch as the Aureomycin media normally contained a relatively high amount of chlorine, such broths contained a relatively small amount of tetracycline.

"By the fall of 1953, it was general knowledge in scientific circles that in the preparation of an Aureomycin broth by the fermentation of *S. aureofaciens*, some percentage of tetracycline was coproduced. This fact was also known by the Patent Office, because its examiners and scientists keep abreast of such developments, but more specifically because it had been disclosed in the three fermentation applications, particularly Minieri, all of which were before the same patent examiner who passed upon the Conover application. In addition, in the fall of 1953, an antibiotics symposium was held, at which the public discussion revealed as general knowledge the fact that tetracycline was inherently produced in Aureomycin broths. However, the fact that tetracycline was present in the resultant product, Auremoycin, was not known at this time and did not become known by the Patent Office until January 3, 1955."

To the contrary, the Commission held:

"The hearing examiner dismissed the above charge for the reason that any misstatements of fact or withholding that the record discloses pertains to matter which was immaterial to the Patent Office's determination of the validity of Conover's product claims. We disagree. *We find that the hearing examiner's decision is based on a misunderstanding of the patent examiner's rulings on tetracycline.* The hearing examiner's entire decision on this phase of the case contains a series of deductions from certain erroneous assumptions. He assumes (erroneously) that the Patent Office examiner, Lidoff, dissolved the second interference and rejected the Conover (Pfizer) product claims on the speculation that tetracycline, as an inherent part of commercial Aureomycin products, had been in *public*

use or on sale more than one year before the date of Conover's application. From this, and from certain conclusions of law based on decisions that Lidoff never relied upon, he reasons that Lidoff must have been interested only in whether tetracycline was present in the final commercial product of Aureomycin and whether it was present in 'substantial quantities' so as to impart utility to that product. From this he reasons that Lidoff's motive in requiring Pfizer to run tests was to determine whether tetracycline was present in the broth in (again) 'substantial quantities' so that such quantities could have been recovered along with Aureomycin. From this conclusion and from erroneous findings that Lidoff always knew of coproduction of tetracycline in smaller amounts (less than 'substantial') in the prior art processes and that Pfizer 'conceded' that tetracycline constituted ten percent of Aureomycin, he reasons that no *material* misrepresentation or withholding of information occurred because the evidence shows that tetracycline almost always constituted something less than ten percent of Aureomycin.

"The Commission contrary to the above conclusions by the hearing examiner, finds that:

"(1) The patent examiner did not reject Conover's product claims on the ground that tetracycline may have been in public use or on sale more than one year before the date of Conover's application, but rather his rejection was based on the ground that it appeared that tetracycline was inherently produced by the fermentation processes described in the Duggar and Niedercorn patents and for the reason of inherent production alone would be unpatentable.

"(2) Nowhere in the documents before the patent office did respondents or the patent examiner even allude to the public use and sale theory.

"(3) The patent examiner informed Pfizer that he would not allow tetracycline product claims unless Pfizer submitted affidavits in which Pfizer scientists swore they could not recover tetracycline from broths representative of those described in the Duggar and Niedercorn patents.

"(4) Pfizer submitted such affidavits and the examiner allowed the claims, thereby enabling Pfizer to obtain a patent on the product tetracycline.

"(5) Pfizer deliberately made false and misleading statements regarding the affidavit tests and suppressed the fact that Pfizer had previously found that tetracycline was produced by one of these fermentation processes.

"(6) The patent examiner did not previously know that inherent production occurred in any of these processes and was not told of this fact by Pfizer, nor did Pfizer concede that tetracycline constituted ten percent of Aureomycin (or any other percentage, for that matter).

"(7) The false statements and information withheld were material to the patent examiner's determination of the patentability of tetracycline and were known by Pfizer to be material.

"To come to any other conclusion would be to torture the English language and make semantics rather than facts the basis for our rulings.

* * *

"[T]he hearing examiner erroneously finds that Lidoff was interested only in whether tetracycline was present in commercial aureomycin products. From this and from certain conclusions of law . . . the hearing examiner reasons that Lidoff must necessarily have been interested only in whether tetracycline was present in commercial products in 'substantial quantities' so as to impart utility to the commercial product."

The hearing examiner concluded that Patent Examiner Lidoff drew a distinction between coproduction or inherent production as applied to process applications on the one hand and product applications on the other, saying:

> "The disclosures of Minieri, Heinemann and Martin-Bohonos, as well as other sources of information, revealed to the patent examiner the fact that tetracycline was inherently produced in Aureomycin broths. The disclosure of Minieri, dealing with fermentations producing substantial quantities of tetracycline, i.e., a process of fermenting *S. aureofaciens* in a media which produced 'concentrations making possible the recovery of the therapeutic product,' led the examiner to speculate that, in following the teachings of Duggar and Niedercorn, since tetracycline was inherently produced in the broths it might have been produced in concentrations making possible the recovery of the therapeutic product. Accordingly, in connection with product claims, he wished to ascertain if this were the fact. If the concentration were sufficient to make possible the recovery of tetracycline in the end product, Aureomycin, then the prior art product might well have possessed the same utility possessed by tetracycline.
>
> "However, the same considerations did not apply with respect to process applications. Most of the Patent Office's rejections of tetracycline claims because of the inherent production of tetracycline under the Duggar and Niedercorn processes for making Aureomycin concerned process applications and not product applications. There are several obvious reasons why the inherent production of tetracycline in any amount in Aureomycin broths would bar claims for process patents substantially the same as the Duggar and Niedercorn processes, but it would unduly lengthen

this decision since it is unnecessary to discuss them here. Whatever the reasons, it is clear that the Patent Office distinguished process claims from product claims with respect to rejections on the basis of inherent production of tetracycline. . . .

"It is clear that the Patent Office, and particularly Examiner Lidoff, distinguished between the amount or substantiality of inherent production in considering its effect upon the patentability of process applications and product applications.

* * *

"It is clear that the patent examiner considered the coproduction of tetracycline with aureomycin in the *process,* i.e. the fermentation of *S. aureofaciens,* as relevant to the process applications, and considered the coproduction of tetracycline in the resultant *product* as relevant in the *product* applications." (Emphasis that of hearing examiner.)

The Commission held to the contrary:

"In support of his conclusion that Lidoff was interested only in knowing whether substantial quantities of tetracycline were coproduced, the hearing examiner theorizes that Lidoff applied different standards for product and process claims—that any amount of prior production would anticipate a process claim, but that only the production of 'substantial' amounts would anticipate a product claim. There is no indication that Lidoff so regarded the law. It appears that the source of this distinction lies in the fact that the hearing examiner, in imputing the 'public use and sale' theory to Lidoff, could not otherwise account for process claim rejections."

The hearing examiner held that Mr. Lidoff was not deceived or misled by the information withheld by Cyana-

mid, but that he already was familiar with all information which Cyanamid is charged with withholding. The Commission held to the contrary.

The hearing examiner placed much emphasis upon the fact that Bristol filed an affidavit with the Patent Office January 3, 1955, six days before the tetracycline patent was issued, disclosing in detail the presence of two to four percent tetracycline in old aureomycin, saying:

> "This disclosure, together with the interview statements of the examiner and the affidavits heretofore considered clearly establish that the Patent Office did not consider the presence of 2 to 4%, or small amounts, of tetracycline in Aureomycin a bar to patentability. It also corroborated the statement made by Pfizer that the resultant product might be assumed to contain 10% or less tetracycline.
>
> "The Taylor affidavit establishes that the Patent Office was not of the opinion that Pfizer had misrepresented or withheld such information from the Patent Office. It was filed with Lidoff, the same examiner handling the Conover applications. Patent Office Rule 313 specifically provides that after a notice of allowance is issued, the application may be withdrawn by the Patent Office on the basis of mistake on the part of the Office or because of fraud or illegality in the application. If, as contended, Pfizer had misrepresented and Pfizer, Cyanamid and Bristol had withheld such information concerning inherent production, this affidavit revealed this information to the Patent Office and in conformity with Rule 313 the patent would not have been issued. In addition, Rule 56 states that any application may be stricken from the files which is fraudulently filed, or in connection with which any fraud is practiced or attempted on the Patent Office. If the Patent Office, as contended, would

not have issued the patent if it had been aware of any inherent production in the prior art, or that such information had been withheld or misrepresented, then the filing of the affidavit would have revealed this, the Patent Office would not have issued the patent, and it would have had serious reason to question the claimed misrepresentation by Pfizer. On the contrary, this affidavit corroborated the statement made by Pfizer that not more than 10% of the recovered product was tetracycline. It also corroborates the finding herein that the patent examiner, as he stated, was interested only in appreciable amounts of tetracycline making possible its recovery as a therapeutic product."

The Commission also disagreed on this point, saying:

"Six days before the issuance of the Pfizer patent on January 11, 1955, Lidoff's division received an affidavit from Bristol (the Taylor affidavit) in connection with Bristol's Heinemann application, which stated that 2 to 4% of tetracycline had been found in Aureomycin products, including the products that had been placed on the market before the date of the Conover discovery of tetracycline. The hearing examiner, at page 88 of his decision, uses this as the basis for his conclusion that Lidoff *knew* that tetracycline was inherently produced and *therefore* he must have ruled that this was not enough tetracycline in old Aureomycin products to impart utility thereto, otherwise he would have taken action to halt the issuance of the patent.

"This reasoning cannot be accepted for several reasons. As explained in our Findings the Taylor affidavit did not refute Pfizer's tests. In addition, Lidoff could not make reference to such an affidavit in rejecting the Conover claim since it was filed in a confidential *ex parte* proceeding. Bristol, in filing the

Taylor affidavit, did not waive its right to secrecy in regard to its Heinemann application. Therefore, Lidoff, even if his suspicions had been aroused by the Taylor affidavit, could not have shown the basis thereof since the only evidence in the Conover file wrapper was an affidavit by an apparently equally reputable scientist as Dr. Taylor which stated categorically that no tetracycline was recovered from the broth fermented with NRRL-2209."

The hearing examiner made the following summary of his findings concerning the inherent production of tetracycline in aureomycin:

"The facts concerning the inherent production of tetracycline in Aureomycin have already been found. It has been found that the Patent Office was aware of the fact that tetracycline was inherently produced in Duggar and Niedercorn fermentation broths and was interested in ascertaining whether appreciable quantities of tetracycline had been produced making possible the recovery of the therapeutic product. It has been found that Pfizer made no misrepresentations to the Patent Office concerning this subject, and in fact advised the Patent Office to assume that as much as 10% tetracycline was present in the product recovered by the Bogert tests. It has been found that tetracycline in fact was present in the prior art product in amounts ranging from 2 to 5% and that this fact was called to the attention of the Patent Office by Britsol's affidavit filed before the issuance of the patent."

The Commission held:

"The Commission, on the basis of the record, cannot accept the hearing examiner's finding that by the fall of 1953 it was known by all, including Lidoff, tha

coproduction occurred in the Duggar and Niedercorn processes. The hearing examiner fails to understand that the fermentation applications submitted to Lidoff concerned processes which allegedly produced tetracycline for the *first time* by fermentation because they differed from the Duggar and Niedercorn processes in that they used an environment substantially free of chloride ions and used newly discovered micro organisms.

* * *

"Throughout his decision, the hearing examiner equates the following terms with one another—'recoverable quantities,' 'appreciable quantities,' and 'substantial quantities.' The record nowhere indicates that Lidoff used the term 'substantial quantities' as signifying what he considered to constitute coproduction. Lidoff never used the term 'appreciable quantities' in his rejections. This term was used only in the 'Remarks' and affidavits filed by Pfizer in December 1954. Hutz, the author of the 'Remarks,' conceded on the witness stand that 'appreciable quantities' was used synonymously with 'recoverable quantities' and it is clear from the context in which the term was used that it was so intended.

* * *

"The Commission, contrary to the above conclusion of the hearing examiner, finds that Pfizer made false statements to the Patent Office and withheld material information. The record shows that Lidoff was not interested in ascertaining any particular percentage figure of coproduction but wanted to know whether tetracycline could be recovered in clearly identifiable form from any of the media described in the Duggar and Niedercorn patents using the deposited microorganism NRRL-2209. The record indicates that Lid-

off believed that Example 28 because of its low chloride ion content, was the most favorable of the media in Niedercorn for the production of tetracycline. Pfizer had discovered from previous tests that little potency was obtained using NRRL-2209 in the Example 28 medium. Dr. Bogert, in October 1954, determined that higher potencies were obtained using Example 1 of Niedercorn and that tetracycline was coproduced with Aureomycin. Neither Bogert nor his superiors revealed this fact to the Patent Office."

Opinion of Commission on Remand

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Paul Rand Dixon, Chairman
Philip Elman
Everette MacIntyre
John R. Reilly
Mary Gardiner Jones

In the Matter of AMERICAN CYANAMID COMPANY, *a corporation;* BRISTOL-MYERS COMPANY, *a corporation;* BRISTOL LABORATORIES, INC., *a corporation;* CHAS. PFIZER & CO., INC., *a corporation;* OLIN MATHIESON CHEMICAL CORPORATION, *a corporation;* and THE UPJOHN COMPANY, *a corporation.*	DOCKET No. 7211

Opinion of the Commission

By Reilly, Commissioner:

An order to cease and desist was issued by the Commission in this matter on December 17, 1963. Thereafter the order was reviewed by the United States Court of Appeals for the Sixth Circuit, and in an opinion issued June 16, 1966, the court vacated and set aside the Commission's decision and remanded the entire proceeding to the Commission for a *de novo* hearing on all issues without the participation of Chairman Dixon.

The complaint herein, filed July 28, 1958, charged respondent Pfizer with making false, misleading, and incorrect statements to, and withholding material information from, the United States Patent Office for the purpose and with the effect of inducing the issuance of a patent on tetracycline, a broad-spectrum antibiotic. The complaint also alleged that Bristol and Cyanamid withheld from the Patent Office material information in the course of the prosecution of patent applications, as a result of which Pfizer was aided in obtaining its tetracycline patent, and that Cyanamid, Bristol, Squibb and Upjohn solicited and accepted licenses from Pfizer under the tetracycline patent, knowing that material information had been withheld from the Patent Office by one or more of the respondents. The complaint further alleged that all five respondents fixed and maintained prices of broad-spectrum antibiotics, including tetracycline, through conspiracy and combination.

On October 31, 1961, Hearing Examiner Robert L. Piper filed an initial decision holding that the evidence failed to establish that respondents had engaged in any of the unlawful practices alleged in the complaint. On appeal, this initial decision was vacated and set aside and on August 8, 1963, the Commission entered its own findings of fact, conclusions of law and opinion. It found that

Pfizer, in securing its tetracycline patent, had deliberately made false and misleading representations to, and withheld information from, the Patent Office and it concluded that this conduct amounted to "unclean hands", "inequitableness", and "bad faith" vis-a-vis the the Patent Office.[1] The Commission further found that Pfizer asserted monopoly rights under its patent in order to prevent competition in the tetracycline market and that the effects of those acts have been to restrain competition, to foreclose a substantial market, and to create a monopoly in the manufacture and sale of tetracycline in violation of Section 5 of the Federal Trade Commission Act.

The Commission also found that Cyanamid made erroneous representations to the Patent Office concerning matters bearing on the patentability of tetracycline, and that although Cyanamid soon discovered that these representations were inaccurate, it did not disclose this fact to the Patent Office until after the tetracycline patent had been granted to Pfizer, thereby aiding the latter in its efforts to obtain a patent. The Commission ruled that Cyanamid's acceptance of a license from Pfizer to make and sell tetracycline with knowledge that it had made false statements of fact to the Patent Office which bore directly on the question of patentability of tetracycline, constituted an illegal attempt on its part to share in a monopoly on tetracycline and amounted to a combination in restraint of trade. Similar charges against Bristol, Squibb and Upjohn were dismissed.

On the issue of price fixing, the Commission held that the record as a whole sustained the charge that all five respondents fixed and maintained the price of tetracycline

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[1] The Commission was also of the opinion that Pfizer was guilty of common-law fraud but found that such a holding was unnecessary to its disposition of the case.

in substantial markets through conspiracy and combination.

In its final order, entered December 17, 1963, the Commission directed Pfizer to license its tetracycline patent to any domestic applicant on a 2½ percent royalty basis and to provide the licensees with certain technical know-how. Under identical terms, Cyanamid was directed to grant licenses for tetracycline production under two Aureomycin patents. All five respondents were prohibited (by order issued in August 1963) from entering into price-fixing agreements and each respondent was directed to redetermine its tetracycline prices.

All respondents appealed from this decision to the United States Court of Appeals for the Sixth Circuit, challenging the Commission's findings, conclusions and order on both the patent and pricing phases of the case. They also claimed that they had been deprived of a fair hearing by reason of Chairman Dixon's participation in the decision. In an opinion filed June 16, 1966, the court held that Chairman Dixon was disqualified to sit in the case and, on the basis of that holding, remanded the case for a *de novo* consideration of the record without the Chairman's participation. Because of the remand, the court expressed no opinion as to whether the Commission's findings and decision with respect to the price-fixing issue were supported by substantial evidence. It did however, pass upon two other issues for the assistance of the Commission on remand. It held first of all that "assuming the facts as found by the Commission to be supported by substantial evidence, the Commission has jurisdiction to require as a remedy the compulsory licensing of the tetracycline and Aureomycin patents on a reasonable royalty basis." And secondly, it held that the Commission's decision to the effect that the tetracycline patent was issued as a result of improper conduct on the part of Pfizer and

Cyanamid, as well as the corresponding portion of the order to cease and desist, was not supported by substantial evidence on the record considered as a whole.

Certain background information is necessary to an understanding of the patent phase of this matter and to the court's ruling with respect thereto. The following facts which are not in dispute are taken in substantial part from the findings as to the facts made by the Commission in its original decision.

Antibiotics are chemical substances produced by certain microorganisms and have the capacity to destroy and inhibit the growth of infectious and disease-producing microorganisms. The earlier antibiotics such as pencillin and streptomycin are known as narrow-spectrum antibiotics because they are normally effective against either gram-positive or gram-negative bacteria, but not both. The antibiotics with which this case is concerned are known, beginning with the discovery of Aureomycin, as broad-spectrum antibiotics because they are allegedly effective against a wider range of bacteria, including both gram-positive and gram-negative bacteria.

At the time the complaint issued, there were four broad-spectrum antibiotics on the market: chlortetracycline, oxytetracycline, tetracycline and chloramphenicol.[2] Each of these is patented. Cyanamid, which is the owner of the patent on chlortetracycline and the sole manufacturer and seller of this product, introduced it on the market in 1948 under the trade name "Aureomycin". Pfizer holds the patent on oxytetracycline and is its sole manufacturer and seller. This antibiotic reached the market in 1950 under the trade name "Terramycin". Tetracycline is the only one of the four antibiotics sold by more than one firm. As

[2] Parke-Davis & Company (not a party to this proceeding) is the patentee of chloramphenicol, which has been sold and manufactured by this concern since 1949 under the trade name "Chloromycetin".

a result of the settlement of a patent interference proceeding, Pfizer, the owner of the tetracycline patent, licensed Cyanamid to manufacture and sell tetracycline. Later on, Bristol, Squibb, and Upjohn were licensed by Pfizer upon settlement of infringement suits brought by the latter.

Aureomycin, Terramycin and tetracycline are produced by the fermentation of microorganisms in aqueous nutrient media. The medium is inoculated with the microorganism, and under controlled and aseptic conditions the microorganism is allowed to grow. After a period of time judged to be optimum for antibiotic yield, the fermentation is stopped and the antibiotics are recovered from the broth. The particular strain of microorganism used will cause variations in yield. Other factors which determine the type and amount of antibiotic substance to be produced are the chemical ingredients of the broth and the conditions under which the fermentation takes place.

The yield of antibiotic content per milliliter of a fermentation broth is commonly called "potency". Potency is usually measured in terms of micrograms (mcg.) per milliliter (ml.). The term "potency" is also used to describe the antibiotic content of solid products that are recovered from a broth. Potency is then stated in terms of micrograms (mcg.) per milligram (mg.).

Aureomycin is made by the fermentation of a species of microcrganism known as *Streptomyces aureofaciens,* hereinafter referred to as *S. aureofaciens.*

Tetracycline can be made either by fermentation or by subjecting Aureomycin to a process of mild catalytic hydrogenation, which removes the chlorine atom from the Aureomycin molecule. This chemical transformation was the original method by which tetracycline was discovered.

The patent covering Aureomycin is the Duggar Patent, U.S. Patent 2,482,055, issued September 13, 1949. (The Niedercorn Patent, U.S. Patent 2,609,329, issued September

2, 1952, is an improvement patent on a process for producing Aureomycin.) Both are owned by Cyanamid. The Sobin Patent, U.S. Patent 2,516,080, covering the product Terramycin, was issued to Pfizer on July 18, 1950; the Conover Patent, U.S. Patent 2,699,054, covering tetracycline, was issued to Pfizer on January 11, 1955.

Prior to 1952, the chemical structures of Aureomycin and Terramycin were unknown. Aureomycin, for instance, was described in the Duggar patent as an "antibiotic substance" and was identified in terms of secondary chemical properties. During the spring of that year, a Pfizer research team headed by Dr. R. B. Woodward of Harvard University, discovered the molecular structure of these two antibiotics. A member of the research team, Dr. Conover, noting the similarity in the structures of the two antibiotics, speculated that it might be possible to develop a new antibiotic by removing the chlorine atom from Aureomycin. By subjecting Aureomycin to mild hydrogenation by means of a catalyst such as palladium, Conover removed the chlorine atom and, in June of 1952, produced tetracycline. On October 23, 1952, Pfizer filed on behalf of Conover an application with the Patent Office for a patent on the deschlorination process and the compound tetracycline *per se*. Thus the product claims were not limited to the tetracycline as produced by Conover's process but were broad enough to read on tetracycline and its salts produced by any process and in any amount.[3]

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[3] The product claims as they were carried over into a continuation-in-part application read as follows (CX 4, p. 8):

"1. A compound chosen from the group consisting of tetracycline, the mineral acid salts of tetracycline, the alkali metal salts of tetracycline and the alkaline earth metal salts of tetracycline.

2. Tetracycline.

3. Mineral acid salts of tetracycline.

4. Alkali metal salts of tetracycline.

5. Alkaline earth metal salts of tetracycline.

6. Tetracycline hydrochloride."

Opinion of Commission on Remand

In 1948, Cyanamid had hydrogenated Aureomycin and obtained a product which it later claimed was tetracycline. In December 1952, Cyanamid repeated its 1948 work and embarked upon a project in which tetracycline was produced from Aureomycin by hydrogenation. On March 16, 1953, Cyanamid filed its Boothe-Morton application for a patent on tetracycline, its salts, and a process for manufacturing it by hydrogenating Aureomycin.

On September 25, 1953, the Heyden Chemical Corporation announced it had discovered an antibiotic, designated HA-20A, which might be tetracycline and that this antibiotic could be produced by direct fermentation. This announcement was the subject of an article which appeared in the *Journal of Commerce* on October 1, 1953. On September 28, 1953, Heyden applied for a patent (the Minieri application) on HA-20A, its salts, and a process for production thereof by fermentation using a newly discovered strain of *S. aureofaciens* and a mutant thereof. As stated above, the patent applications filed by Pfizer and Cyanamid disclosed a process for manufacturing tetracycline by hydrogenating Aureomycin. The Minieri application, however, was apparently the first discovery that tetracycline could be made by direct fermentation. This application disclosed that the microorganism used to prepare tetracycline belonged to the species used in producing Aureomycin and that Aureomycin was coproduced in the Minieri fermentation process. It was on the basis of this information that the patent examiner handling the various tetracycline applications speculated that tetracycline was coproduced with Aureomycin in the processes disclosed in the Duggar and Niedercorn patents.[4]

[4] On November 4, 1953, Cyanamid purchased Heyden's antibiotic division thereby acquiring the rights to the Minieri tetracycline patent application.

Opinion of Commission on Remand

An application for a patent on tetracycline and a process for producing it by fermentation was filed by Bristol on October 19, 1953 (the Heinemann application). Both product and process claims in this application were rejected by the Patent Office on December 8, 1953, on the ground that it appeared that tetracycline had been coproduced with Aureomycin in the Duggar and Niedercorn fermentations.

On November 16, 1953, Harvey Edelblute, Cyanamid's house counsel who was then prosecuting the Boothe-Morton application, had an interview with H. J. Lidoff, the patent examiner who was also handling the Cyanamid and Pfizer tetracycline patent applications. Lidoff inquired about the possibility that tetracycline may have always been concomitantly produced by Cyanamid in its production of Aureomycin, and in response to this inquiry, Edelblute filed a statement in December 1953 assuring the examiner that Cyanamid had investigated the matter and had determined that coproduction did not occur.

On December 28, 1953, Lidoff declared an interference between Pfizer's Conover application and Cyanamid's Boothe-Morton application. Under Patent Office rules, an interference is a proceeding conducted for the purpose of determining priority between two or more applicants claiming the same invention. This interference was terminated on February 9, 1954, following the execution of an agreement between Pfizer and Cyanamid providing for cross-licensing of all patents covering tetracycline and its preparation by the deschlorination process regardless of which party secured the patent. After an exchange of evidence as to priority of invention of tetracycline, Cyanamid conceded that the Pfizer (Conover) application had priority in time and withdrew its Boothe-Morton application.

A second interference was declared by Lidoff on March 2, 1954. In this connection, Bristol had filed continuation applications in the Heinemann matter in January 1954,

claiming tetracycline hydrochloride, and had persuaded the patent examiner that tetracycline hydrochloride was patentably distinguishable from tetracycline. The purpose of this second interference was to determine who had priority on the discovery of tetracycline hydrochloride and the parties to it were Pfizer (Conover application), Bristol (Heinemann application) and Cyanamid (Minieri application).

On October 14, 1954, Examiner Lidoff granted motions by Pfizer and Cyanamid to dissolve the second interference and, on his own motion, ruled that tetracycline hydrochloride was not patentable to any of the parties because it appeared that tetracycline and its hydrochloride were inherently coproduced in the fermentation processes described in the Duggar and Niedercorn patents. The patent examiner stated in this connection:

> "* * * The interference count is unpatentable over the disclosures of Duggar US 2,482,055, Sept. 13, 1949 and Niedercorn US 2,609,329, Sept. 2, 1952, and the interference is dissolved. Duggar and Niedercorn each produce an antibiotic, disclosed as 'Aureomycin' by a fermentation process employing *Streptomyces aureofaciens* and mutants thereof. The antibiotic is identified as an antibiotic by assay against bacteria. It appears from the disclosure of Minieri et al (a party to this interference in an application available to all the parties) that tetracycline is *also* produced in such a fermentation process and that larger proportions thereof are produced when the amount of chloride in the fermentation medium is low (see page 1, lines 5 to 20 and lines 24 to 28 and pages 12, 16, 17, 18 and 19 of Minieri et al S.N. 382,637). Minieri et al clearly and specifically disclose that the microorganism used to prepare *tetracycline* belongs to the Duggar et al US 2,482,055 species and that 'the characteristics are identical with those exhibited by a known culture of

> *S. aureofaciens.*' While neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate, and disclose, that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes (see In re Lieser 1947 C.D. 447; and Allen et al v. Coc 1943 C.D. 55). It has long been held that a purer form of an old product is not inventive and the (apparent) mixture of the prior art meets the count (see Parke Davis v. Mulford 189 F 95 and In re Kebrich 96 USPQ 411)." (Emphasis in original.)

On October 15, 1954, one day after the dissolution of the second interference, Dr. Murphy, a former Pfizer research chemist who was then employed by Pfizer as a patent agent, issued memoranda to two Pfizer scientists, Dr. Fred Tanner and Dr. Virgil Bogert, instructing them to conduct work on the question of coproduction of tetracycline with NRRL-2209, the strain of *S. aureofaciens* which had been deposited by Cyanamid in the public culture collection of the Northern Regional Research Laboratory maintained by the Federal Government. It was made clear to these scientists that the work was in connection with the prosecution of the Conover application and that the results might be used in preparing affidavits for the Patent Office. Tanner was instructed to summarize all fermentation work that had been conducted to date with NRRL-2209, "particularly with respect to the proportion of Aureomycin and tetracycline produced in media specifically described or generally disclosed in the Duggar and Niedercorn Aureomycin patents" (CX 55). He was also instructed to conduct fermentations with NRRL-2209 in accordance with the examples set forth in the Duggar and Niedercorn patents and to have each fermentation broth checked for total broad-spectrum antibiotic potency. Bogert in turn

was instructed to recover and purify, by the Pidacks Florisil-column method,[5] the antibiotics present in the fermentation broths prepared by Tanner and to determine the total broad-spectrum potency. He was also told to determine the Aureomycin and tetracycline content of the recovered products (CX 57).

Pursuant to instructions Tanner conducted fermentations of all the process examples in Duggar and Niedercorn and found that only two broths possessed significant antibiotic potency. Both of these broths were prepared in accordance with the specifications set forth in Niedercorn Example 1. One of these broths possessed an antibiotic potency of 75 micrograms per milliliter and the other, 30 micrograms per milliliter. Taking the higher potency broth, Bogert applied a modified Pidacks procedure and obtained a number of fractions which were found by paper chromatography[6] to contain tetracycline (CX 58). Bogert testified that these tests showed tetracycline to be present and to be present in quantities "of approximately five percent" (Tr. 4412).

The record also shows that in September of 1954, Tanner, as part of a general research project to determine the production of tetracycline by various means of fermenta-

[5] The Pidacks Florisil-column procedure, a column chromatography procedure disclosed in the Duggar patent as a method of recovering Aureomycin from a fermentation broth, involves a process by which the filtered fermentation liquor is passed through a column filled with a substance to which the antibiotics adhere as the broth passes over it. The column is then "eluted" (washed-out) with a proper solvent. As the solvent, containing both antibiotics and impurities, comes out of a column, it is segregated in portions called "bands" or "fractions". Dr. Bogert, in a test run on a Niedercorn broth in November 1954, determined that most of the tetracycline present is destroyed when one strictly follows the Pidacks procedure, but that the result could be obviated by a slight modification of the procedure.

[6] Paper chromatography is a method that can be used for identifying tetracycline and many other substances. It consists of placing

tion, had fermented NRRL-2209 in a Niedercorn Example 28 medium and had found the resulting broths to be less than 10 micrograms per milliliter (RPX 12B). These broths were so poor in antibiotic potency that they were classified as containing no Aureomycin or tetracycline (Tr. 4129-4130). On the other hand, as in the aforementioned October work, Tanner obtained potencies from Niedercorn Example 1 that exceeded 70 mcg./ml.

On November 24, 1954, Examiner Lidoff officially rejected the product claims in the Conover application (then in an *ex parte* status) by carrying over *verbatim* his ruling in the second interference that the claims were unpatentable because tetracycline was apparently coproduced in the Duggar and Niedercorn processes. He did allow the process claims, however, recognizing that Conover's method of converting chlortetracycline (Aureomycin) into tetracycline merited patent protection. The misrepresentations and withholdings that are involved in this case concerned only the product claims, which as previously noted, were broad enough to cover the compound "tetracycline" produced by any process and in any amount.

On November 29, 1954, Werner H. Hutz, Pfizer's outside patent counsel handling the Conover application, and Dr. Murphy conferred with the patent examiner. In accordance with Patent Office practice, a summary of what

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a spot of the material being examined on a strip or sheet of filter paper and allowing a solvent to flow over the paper by capillary action. The paper is removed from the solvent, immobilizing spots of the material which have migrated. Previous tests have established that tetracycline and other products have certain characteristics in the rate at which they migrate. The results of the paper chromatography can be compared against the standards. Paper chromatography can also be used to determine the percentage of tetracycline present in a mixture by measuring the zone of inhibition of the bacteria test organism.

transpired at this conference was drafted and filed by Hutz at the next conference on December 8, 1954:

> "At the outset of the interview, the Assistant Examiner agreed that the discovery of the new antibiotic, tetracycline (and its salts), constituted a major advance in the art, that should merit patent protection. He further conceded that neither the Duggar nor the Niedercorn patents contains any disclosure whatsoever of this important new antibiotic nor the slightest hint as to the possible existence thereof. However, he stated that applicant's product claims appeared to be anticipated by the possible, although wholly unappreciated, co-production of appreciable amounts of tetracycline in the fermentation processes described in the cited patents.
>
> "It was pointed out to the Assistant Examiner that there is no reasonable basis for his speculation as to the co-production of tetracycline in the prior art processes, and that the same rejection had previously been made and withdrawn in the prosecution of the Heinemann et al. application. . . . The Examiner, however felt that he was justified in relying upon the disclosure of the Minieri et al. application Serial No. 382,637 as giving rise to a rebuttable assumption of inherent production.
>
> "Applicant's counsel denied that any such prima facie assumption is justified. He pointed out that there are no statements whatever in the Minieri et al. application to the effect that most strains of *Streptomyces aureofaciens* are capable of producing tetracycline under previously known fermentation conditions. Minieri et al refers specifically only to the use of a new strain (Texas organism) and a mut[illegible] thereof (Strain UV-8) that are obviously not the same as the known

strain deposited by Duggar and identified as NRRL-2209. On page 14, second paragraph of their disclosure, when speaking of the possible use of other strains, Minieri et al state that such are limited to those which produce tetracycline 'in concentrations making possible the recovery of the therapeutic product'. This is certainly no indication that the NRRL-2209 strain possesses such ability, particularly under the conditions described in the Duggar and Niedercorn patents.

"The available evidence is overwhelmingly contrary to the Examiner's assumption. Minieri et al themselves, in their brief on their motion to add fermentation counts in the interference . . . have stated that tetracycline could previously be produced only by deschlorination, and that there is no evidence of inherent production by the prior art processes. Most striking of all is the fact that the assignee of the Duggar and Niedercorn et al patents, who manufactured literally tons of chlortetracycline (Aureomycin) according to the methods described therein, failed to discover any tetracycline in such large-scale manufacture, although it devoted extensive research to the recovery, purification and properties of its patented antibiotic. Said assignee first claimed tetracycline (and its salts) made by a *deschlorination* process in its Boothe et al application Serial No. 342,556 filed March 16, 1953, some five years after the Duggar and Niedercorn patents were filed. This should conclusively refute the tenuous basis for the Examiner's unwarranted assumption.

"It was further submitted to the Examiner that there is no proper basis in law for his rejection, even assuming that his speculation as to inherent co-production were correct. There are numerous court decisions establishing the rule that 'novelty is not

negatived by any prior accidental occurrence or production, the character and function of which was not recognized until later than the date of the patented invention sought to be anticipated thereby' (1 Walker, 5th Ed., Sec. 106). It follows that a wholly unrecognized occurrence of some ineffective amount of tetracycline in a prior art product could not anticipate applicant's claims. The disclosure or use of such a product as an antibiotic makes no difference, since it would display none of the distinctive properties that make tetracycline such an important advance in the art.

"Despite the foregoing arguments, the Examiner adhered to his position that he would not withdraw his rejection of the product claims, unless applicant submits a showing overcoming his speculated basis for such rejection. He explained that he would require evidence that fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the deposited strain NRRL-2209, do not contain recoverable amounts of tetracycline. He stated that the absence of such amounts of tetracycline would have to be established by failure to recover this antibiotic in a clearly identifiable form according to present day efficient methods for the separation thereof from fermentation broths.

"While applicant's counsel did not concede that there is any necessity for such a showing, he ventured the opinion that it could be made and stated that he would explore the matter in view of the great urgency of this case. The Examiner made it clear that he would not insist on a categorical averment that the fermentation broths prepared according to the cited patents contain no tetracycline whatsoever. He evidently appreciates the impossibility of proving its

non-existence and is not concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic."

After the oral interview of November 29, 1954, Murphy notified Tanner and Bogert that tests were to be conducted for the Patent Office to determine whether tetracycline could be recovered from Duggar and Niedercorn Example 28 broths using three recovery procedures described in the Bogert-Walsh, Minieri, and Heinemann applications. After these tests had been completed, Pfizer submitted affidavits to the patent examiner, executed by Bogert and Tanner, informing him that they had not been able to recover products clearly identifiable as tetracycline from the Example 28 fermentation broths. After examining the affidavits, the patent examiner requested more information as to the possibility of recovering tetracycline. The next day, December 9, Hutz and Murphy conferred again with the examiner. They submitted a supplemental affidavit signed by Bogert and filed the following remarks:

"As regards the affidavit of Dr. Bogert, the Examiner indicated that the details of the tests referred to at the middle of page 3 should be supplied. He further required that some explanation be furnished why no further efforts were made to separate and recover clearly identifiable tetracycline from the various amorphous materials showing some degree of biological potency, that were recovered in the various procedures described. It was immediately pointed out to him that the amount of materials were so small and their potencies so low in each case, that it would be futile to attempt to recover identifiable tetracycline therefrom by known procedures. He requested that such explanation be set forth in affidavit form, and

it was agreed that a supplemental affidavit by Dr. Bogert to this effect would be made of record.

"Such supplemental affidavit is submitted herewith. . . . It explains why no further efforts were made to work up the small amounts of amorphous materials recovered, instead of the crystalline tetracycline or at least high potency crude tetracycline that should have been obtained had the broths contained appreciable amounts of this antibiotic."

Bogert's supplemental affidavit recited that he had applied an acid color test which should show whether an amorphous product recovered from one of the broths contained 20 percent or more tetracycline. He concluded:

"Based on these results and on his experience with the results of a great many such tests on materials containing tetracycline, chlortetracycline and mixtures thereof, he is convinced that not nearly as much as 20% of the potency of the amorphous material could be due to the presence of tetracycline, in fact there was no indication whatever of the presence of tetracycline. Assuming that the maximum possible proportion of the total potency due to tetracycline is 10%, this means that the 0.36 grams of amorphous material cannot contain more than about 0.009 grams of tetracycline. He does not know of any method whereby any part of such a minute amount of tetracycline could be separated and recovered in clearly identifiable form from the amorphous material."

On the basis of the assurances given in the aforementioned affidavits and Remarks, the patent examiner on December 9, 1954, granted a notice of allowance to Pfizer and the tetracycline patent was issued to Pfizer on January 11, 1955.

Opinion of Commission on Remand

In holding that neither Pfizer nor Cyanamid was guilty of any impropriety in dealing with the Patent Office, Hearing Examiner Piper (in the first initial decision in this matter) was of the opinion that Lidoff's rejection of the tetracycline product claims was based on the speculation that tetracycline had imparted utility to commercial Aureomycin and therefore had been in prior public use or on sale, grounds for rejection under Section 102(b) of the Patent Code, 35 U.S.C. 102(b). He found that Lidoff was aware that tetracycline was inherently produced in Aureomycin fermentation broths and that he was interested only in whether tetracycline was present in commercial Aureomycin products. He reasoned that Lidoff must necessarily have been interested only in whether tetracycline was present in commercial products in "substantial quantities" so as to impart utility to the commercial product. He further reasoned that since Lidoff had referred to those portions of Minieri which demonstrated the presence of tetracycline in quantities of 50 percent or more of the antibiotic present the patent examiner "must have assumed logically that this might have occurred under Duggar and Niedercorn and therefore was speculating that it might have been present in such substantial quantities" (Initial Decision, p. 57). He concluded that "no matter what fermentations were prepared or recovery methods applied, they could only have established at the most that the resultant product contained less than 10 percent tetracycline, the amount Pfizer requested the patent examiner to assume. Pfizer did not withhold or misrepresent any information concerning inherent production" (Initial Decision, p. 66).

The Commission, on the other hand, held that there was no basis in the record for the hearing examiner's finding that Lidoff had rejected the Conover application on the ground that tetracycline may have imparted utility to the commercial product Aureomycin. It held instead that

Lidoff had speculated that Conover had discovered a product which had already existed in prior art fermentation processes that were described in prior patents (Duggar and Niedercorn) as producing an "antibiotic substance" and for this reason lacked novelty and could not be patented under 35 U.S.C. 102(e) and (f). It specifically held in this connection that "The record clearly shows that Lidoff's rejection was based on the theory that the description in prior art patents of a process which is disclosed as producing antibiotic substance, part of which is tetracycline, constitutes an anticipation of any later product claims for tetracycline." According to the Commission, therefore, the purpose of the affidavit tests was to ascertain whether any perceptible or identifiable amount of tetracycline could be recovered, extracted, or isolated from the broths, or from any amorphous product recovered from the broths, using the best methods available for this purpose. It further found that Pfizer's representatives had argued to Lidoff that there was no reasonable basis for his assumption of coproduction and that, in response to this argument, the patent examiner stated that he would withdraw his rejection of Pfizer's tetracycline product claims if Pfizer could demonstrate that tetracycline could not be recovered in clearly identifiable form from fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the strain *S. aureofaciens* NRRL-2209. The Commission also found that although Lidoff may have believed that Niedercorn Example 28, because of its low chloride ion content, was the most favorable of the media for the production of tetracycline he was interested in the possible production of tetracycline in any of the Niedercorn examples.

The Commission's conclusion that Pfizer had violated Section 5 was based on the finding that Pfizer's representatives failed to disclose to Lidoff, although under a duty

to do so, that Pfizer had discovered from previous tests that NRRL-2209 fermented in a Niedercorn Example 28 medium produced broths which were so poor in antibiotic potency that they were classified by Pfizer as containing no Aureomycin or tetracycline, whereas fermentation of NRRL-2209 in a Niedercorn Example 1 medium produced a broth of much higher potency which was found to contain tetracycline; that Pfizer's representatives withheld the fact that the broths used in the affidavit tests were unusually low in potency and that the pH of one of the broths exceeded the optimum limits prescribed in the patent during the first part of the fermentation; that Pfizer's representatives had falsely represented that "the available evidence is overwhelmingly contrary" to the examiner's assumption of coproduction; that they falsely stated that the two broths described in Tanner's affidavit were "representative" of the Duggar and Niedercorn broths; and that they falsely stated that the recovery procedures used by Bogert were the best designed for recovering any tetracycline present in the test broths.

With respect to Cyanamid, the Commission held that this respondent had made false statements of fact to the Patent Office concerning the coproduction of tetracycline in commercial Aureomycin. It held that although disclosure by Cyanamid of the presence of tetracycline in commercial Aureomycin would not conclusively have proven the existence of recoverable amounts of tetracycline in NRRL-2209 fermentations, the denial by Cyanamid of such coproduction aided Pfizer in its endeavor to convince the patent examiner that tetracycline was a new product that did not exist in the prior art. Under these circumstances, the Commission found Cyanamid's acceptance of a license under the Conover patent constituted an illegal attempt on its part to share in a monopoly on tetracycline.

In its review of the Commission's decision the court expressed the opinion that only Lidoff could conclusively

settle the issue as to whether Pfizer and Cyanamid had made misrepresentations and withheld essential information bearing on the question of the patentability of tetracycline. It pointed out that "with no testimony available from Mr. Lidoff, the hearing examiner and Commission drew opposite inferences and reached opposite conclusions as to what the patent examiner knew, intended, and required in the processing of the patent applications." The court therefore held that the decision of the Commission on the patent issue was based upon "inferences and speculations which are insufficient to constitute substantial evidence." It suggested that Lidoff be called "as a witness to testify as to facts known only to him with respect to material issues of great public interest in this proceeding."

After remand from the court, the Commission, by order of August 1, 1966, reopened the proceeding and remanded it to the Chief Hearing Examiner for assignment to an examiner[7] to begin hearings for the "sole and limited purpose of receiving the testimony of Patent Examiner H. J. Lidoff, and of any other witnesses who have heretofore testified, with respect to 'the issue as to whether Pfizer and Cyanamid made misrepresentations to the Patent Office and withheld essential information, thereby deceiving Lidoff into granting a patent which otherwise never would have been approved.'" Pursuant to these instructions, a hearing was held before Hearing Examiner Abner Lipscomb at which Mr. Lidoff was presented as a witness by counsel supporting the complaint, and Werner H. Hutz and Dr. Francis X. Murphy were presented as witnesses by Pfizer.

In an initial decision filed November 9, 1966, the hearing examiner, relying principally on the testimony of Mr. Lidoff, made findings of fact which are in complete accord

[7] Hearing Examiner Piper was no longer in the employ of the Commission at this time.

with the earlier findings of the Commission with respect to the state of Lidoff's knowledge concerning coproduction of tetracycline in prior art processes and with respect to the basis for Lidoff's rejection of the tetracycline product claims in the Conover application. Lidoff testified in this connection that as of December 9, 1954, and prior thereto he did not know as a fact that any tetracycline was inherently produced in the Duggar and Niedercorn patent fermentations; that he had speculated on the basis of information contained in the Minieri application that some tetracycline was present in the fermentation broths made pursuant to the teachings of Duggar and Niedercorn; that if tetracycline was inherently produced by these prior art processes and could be identified in the broths he was of the opinion that it lacked novelty and could not be patented; that Hutz and Murphy had vigorously denied at the time that such coproduction occurred; and that the factual question that he was attempting to get answered was whether identifiable tetracycline was or was not present in the broths of the Duggar and Niedercorn patents. Above all, he testified that had he been told by Pfizer that 5% of the antibiotic content of a Niedercorn Example 1 broth was tetracycline he would never have allowed the patent. He further testified that if he had known that commercial Aureomycin contained tetracycline he would have also rejected the Conover application on a different and additional statutory ground.

In his initial decision the hearing examiner, relying primarily on Lidoff's testimony, concluded that representatives of Pfizer and Cyanamid had made false and misleading statements to Patent Examiner Lidoff and had suppressed and withheld information from him all of which was relevant and material to his consideration of Pfizer's application for a patent on tetracycline. He further concluded that Pfizer's misrepresentations and withholding of essential information caused the Patent Office to issue

a patent on tetracycline that otherwise never would have been issued and that similar conduct on the part of Cyanamid aided Pfizer in securing this patent.

Pfizer's Appeal

The first contention made by Pfizer on its appeal from Hearing Examiner Lipscomb's initial decision is that Lidoff's testimony was not based on his recollection of what occurred during his interviews with Hutz and Murphy and therefore should not have been admitted into evidence. In making this argument Pfizer relies on certain statements made by Lidoff on cross-examination which, according to Pfizer, establish that he was totally unable to refresh his memory. We find this argument to be wholly without merit. While Lidoff frankly conceded that after 11 years he could not recall the details of one interview out of several hundred, an examination of his testimony reveals that his recollection of the substance of what occurred in connection with the tetracycline application was quite clear. There is no basis for Pfizer's claim that his mind was a "complete blank" and that he "remembered absolutely nothing". Mr. Lidoff testified not only from a reconstruction of events based on the official Patent Office file, but also as he put it, "on what I know, my feelings and views of what patent practices were at the time" (Tr. 11,541). As the court observed, the answer to the question of whether disclosure of the 5 percent coproduction would have been material to Lidoff was something "known only to him." His testimony is unequivocal that he was interested in the coproduction of any amount of identifiable tetracycline and had he been informed by Pfizer that coproduction in fact occurred he would never have allowed the patent to issue. His testimony on this point is supported by his own written office action of November 24, 1954, *supra* p. 9, the language of which embraces any identifiable amount of coproduction of tetracycline. The hearing examiner found that Mr. Lidoff

was entirely credible and that his testimony "which was presented clearly and unequivocally, explains the numerous factual problems that confronted both the Commission and the Court in their evaluations of the original record; and it supplements and explains clearly proven facts in the record." We agree with the examiner.

Pfizer next contends that Lidoff's testimony is entitled to little weight because it is inconsistent with the testimony of Hutz and Murphy and with the contemporaneous Patent Office record, i.e., the Remarks drafted by Hutz which set forth the substance of the conference with Lidoff on November 29, 1954. This is a rather surprising argument since Lidoff's testimony corroborates in every significant detail the earlier findings of the Commission which were based on the Remarks. But Pfizer nevertheless contends that Lidoff's testimony to the effect that he was interested in the coproduction of any indentifiable tetracycline is in conflict with the Remarks (which he had reviewed and apparently approved) which, according to Pfizer, stated that he was interested only in the coproduction of larger quantities of tetracycline which could be recovered by procedures "then recommended for the recovery of useful amounts of tetracycline from fermentation broths." We do not agree. There would be an inconsistency between Lidoff's testimony and the Remarks only if words and phrases in the Remarks are taken out of context and given the meaning which Pfizer wants them to have.

Pfizer states in its brief that the Remarks describe Lidoff "as having no interest in 'useless trace amounts' of tetracycline . . . but his recent testimony is directly to the contrary. He now insists that, 'the proportion or amount was not significant. The presence was the important thing' . . . the 'percentage is insignificant' . . .". When read in context, however, the memorandum of the conference between Lidoff and the Pfizer officials reveals,

as Lidoff had testified, that the information which he had requested was whether tetracycline was present in broths produced pursuant to Duggar and Niedercorn. According to the Remarks, Pfizer's representatives had argued to Lidoff that the legal basis for his rejection was wrong and that the Conover claims could not be anticipated by a "wholly unrecognized occurrence of some ineffective amount of tetracycline." This certainly does not indicate that Lidoff had based his rejection on the assumption that large quantities or useful, effective amounts of tetracycline were coproduced by the prior art processes as Pfizer now contends. To the contrary, it is obvious that Lidoff's rejection had been based on the belief that the occurrence of even some "ineffective" amount of tetracycline (an amount which "would display none of the distinctive properties" of tetracycline in therapeutic form) would be sufficient to anticipate Conover's claim. Consequently, he would not have required proof that large quantities or therapeutically useful amounts of tetracycline could not be recovered unless he had been persuaded by Hutz's arguments that he was wrong as a matter of law.[8] But the Remarks show that

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[8] When asked at the remand hearing what was meant by "ineffective amounts" Hutz testified that this "could be something more than appreciable but less than effective", an amount which would be insufficient to "display the distinctive properties that make tetracycline such an important advance in the art" (Tr. 11669), thereby contradicting Pfizer's definition of "appreciable" amounts as "amounts which have some usefulness, amounts which impart to the product in which they are contained the antibiotic effect of tetracycline" (Tr. 11589).

Dr. Murphy's testimony on this point is most revealing: "Q. Why were you talking with Mr. Lidoff about ineffective amounts if he was not interested in ineffective amounts? A. Well, he indicated that he was not interested in trace amounts, useless material—Q. Useless material. Ineffective amounts? A. Ineffective material * * * Q. You testified that he was interested in recoverable amounts. You testified that ineffective amounts were not recoverable. And yet you were arguing with him about amounts that were not recoverable. Why were you doing this? A. I don't recall" (Tr. 11709-10).

Lidoff did not change his mind. They state that despite Hutz's arguments "the examiner adhered to his position that he would not withdraw his rejection of the product claims, unless applicant submits a showing overcoming his speculated basis for such rejection."

Lidoff then explained, according to the Remarks, that "he would require evidence that fermentation broths produced strictly in accordance with the Duggar and Niedercorn disclosures, using the deposited strain NRRL-2209, do not contain recoverable amounts of tetracycline" and that "the absence of such amounts of tetracycline would have to be established by failure to recover this antibiotic in a clearly identifiable form according to present day efficient methods for the separation thereof from fermentation broths." It becomes quite clear at this point in the Remarks that the recovery or separation of tetracycline from the broths was to be made solely for the purpose of identification.

It is obvious from Lidoff's testimony that he believed that a separation of the substance was necessary for its positive identification:

> Q. You stated that you considered these analytical techniques to be recovery procedures, is that so? A. I said that in my view, the language "recovery" would also encompass procedures of this nature which separate the material from other materials in order to determine whether or not it is there.
>
> * * *
>
> Q. Now, isn't it a fact that many of these analytical techniques do not recover any product whatever, but actually destroy the product that they are looking for?

> A. Completely analysis would obviously do that. Infra red would probably not recover. Yes, there are methods of identification that would not involve recovery. But as I said earlier, recovery is the preponderant method of identifying a material. That is when you identify materials, the normal procedure would be a form of recovery. The largest number of methods employed at that time would have been a form of recovery broadly (Tr. 11558-11559).[9]

The Remarks then state that "The Examiner made it clear that he would not insist on a categorical averment that the fermentation broths prepared according to the cited patents contained no tetracycline whatsoever." And the reason that Lidoff did not so insist was not because he was uninterested in even the most minute amount of tetracycline but because he appreciated "the impossibility of proving its non-existence". Here again the Remarks make it clear that Lidoff was interested solely in knowing whether tetracycline existed in the prior art fermentations.

The statement is then made in the Remarks that Lidoff was not "concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic." The key words in this clause are not "useless trace" amounts as Pfizer would have us believe. When read in context these words are meaningless. Lidoff was concerned with *identifiable* tetracycline and since he equated separation of tetracycline with positive identification of that substance the significant

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[9] Lidoff also testified that he regarded paper chromatography as an identification procedure which involved the separation of a product from other materials in a mixture. (See Tr. 11560)

words in the sentence are "amounts which cannot be separated from the broths" by known tetracycline recovery procedures.[10]

We also find there is no substance to Pfizer's claim that there is evidence that Lidoff wanted Pfizer to use commercial or industrial type recovery procedures. The record conclusively establishes that Lidoff was interested in the separation and recovery of tetracycline in clearly indentifiable form by whatever method it could be achieved.

We note first of all, despite Pfizer's argument to the contrary, that Lidoff is correct in his view that Craig countercurrent[11] is a recovery procedure as well as an analytical technique. Dr. Woodward, one of the scientists called by Pfizer, testified as follows with respect to Craig countercurrent:

> Q. Is Craig Counter-current distribution an analytical technique or a recovery procedure? A. That is also an exceedingly valuable analytical technique, occasionally used for the recovery of materials in very small amounts (Tr. 4586).

The record also shows that after Lidoff had examined Bogert's first affidavit he required an explanation why further attempts were not made to separate and recover tetracycline from an amorphous product which had been

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[10] As Lidoff pointed out in his testimony, the words in the Remarks are not his words but are the words of Pfizer's officials. It is clear, however, that the summary of what transpired at the conference is sufficiently accurate that Lidoff, having no reason to suspect that Pfizer might later place a different interpretation on them, could accept the Remarks without question.

[11] The Craig countercurrent separation procedure is a method which can be used to separate tetracycline from Aureomycin. It is based on the manner in which a substance will distribute itself between two immiscible solvents. Two substances which have different distribution coefficients, such as tetracycline and Aureomycin can be separated by this method.

separated from one of the test broths. This amorphous product which was extremely small and weak in potency was described as follows in Bogert's affidavit: "A total of 0.36 grams of material having a potency of about 260 micrograms per milligram as chlortetracycline [Aureomycin] was obtained. This product was tested in a manner that he knows is capable of detecting even a small proportion of tetracycline in the presence of chlortetracycline and showed only chlortetracycline." According to the Remarks, it was pointed out to Lidoff that the amount of material was so small and the potency so low "that it would be futile to attempt to recover identifiable tetracycline therefrom by *known procedures*" (emphasis added). And in a second affidavit Bogert stated that even if "the maximum possible proportion of the total potency due to tetracycline is 10 percent, this means that the 0.36 grams of amorphous material cannot contain more than about 0.009 grams of tetracycline. He does not know of *any method* whereby any part of such a minute amount of tetracycline could be separated and recovered in clearly identifiable form from the amorphous material" (emphasis added). It is quite obvious from the reference to "known procedures" and "any method" that Lidoff was interested in the separation or isolation of tetracycline by any procedure and that Pfizer's officials were well aware of that fact.

In light of this evidence we are not persuaded by the testimony of Hutz and Murphy and by Pfizer's contention based thereon that Lidoff was not interested in the recovery or separation of tetracycline by methods other than those which would be feasible for large scale use or which would permit direct recovery of tetracycline from fermentation broths. Also Pfizer's contention that Lidoff was not interested in certain isolation procedures which it has characterized as sensitive analytical techniques must fall in the face of this evidence and the testimony of Dr. Murphy. It is noted that Dr. Murphy testified as follows

with respect to one of these procedures, column chromatography:

> THE WITNESS: I would not regard column chromatography as a generally applicable recovery method. It is rarely, if ever, used in industrial practice for large scale use, and by recovery process I am referring to methods that are applicable on a large scale.
>
> It can be used on a moderate scale to recover a few grams, maybe a hundred grams, but certainly not a commercial recovery process.

Pfizer has thus placed itself in the position of arguing that a procedure such as column chromatography which is capable of recovering a hundred grams of tetracycline would have been rejected by Lidoff as a sensitive analytical technique when its own Remarks and affidavits show that Lidoff was interested in the recovery from less than 1/10 of a gram of antibiotic substance.

We also note that Pfizer attaches great significance to the fact that Bogert's affidavit told Lidoff that even if it be assumed that 10 percent of the potency of the amorphous product was due to tetracycline, the product could not contain more than .009 grams of tetracycline and he did not know of any method whereby he could separate and recover such a small quantity. This statement, however, as Lidoff pointed out, cannot be construed as an admission that coproduction of tetracycline actually occurred. Nor does it represent any sort of statement that tetracycline might have been coproduced in the *broths* in amounts up to 10 percent. And it is the broths which are significant here since Pfizer had actual knowledge that 5 percent of a Niedercorn broth consisted of tetracycline. There is no correlation between hypothetical percentages in amorphous materials and the broths from which they were taken, since the amorphous materials resulted from application of procedures that favored the recovery of tetracycline only. Even Hutz

acknowledged this fact (Tr. 3767-73) and conceded that the interpretation which Pfizer now urges upon us is an invalid one:

> "Q. So, do you agree, then, that the supplemental affidavit did not tell the Patent Office Examiner that ten percent of the antibiotic product produced in broths 1771A and 1771B was tetracycline? A. I do not think it stated that.
>
> Q. It did not state that, did it? A. I don't think so" (Tr. 3777).

The reference in the supplemental affidavit to 10 percent of one particular amorphous product in no way can be construed as showing that Lidoff was not interested in amounts below 10 percent where tetracycline was clearly identified. If the quantity of amorphous material in question (having a potency of 260 micrograms per milligram) had been small enough, Bogert could have truthfully told Lidoff that assuming the maximum possible proportion of the total potency due to tetracycline is 50% or 75% or more, this means that the material contains less than .009 grams of tetracycline and that such a minute amount cannot be recovered in clearly identifiable form. This would certainly not indicate that Lidoff was not interested in the coproduction of tetracycline in these percentages.

Pfizer also contends that Lidoff frequently changed position with respect to the patentability of tetracycline and that he therefore had no firm view of the law on which he based his rejection of the Conover patent application. Consequently, it claims that Lidoff's testimony is entitled to no weight since Lidoff admitted that it was based on a reconstruction of his views of "the principles of patentability."

The record reveals, however, that Lidoff changed his mind only as to the facts and not as to the principle of law involved. His rulings were changed solely on the

basis of factual information supplied by respondents and are consistent therewith as noted in the Commission's first decision in this case (Opinion, pp. 36-38). For example, Lidoff's ruling that tetracycline hydrochloride was patentably distinguishable from tetracycline (referred to on page 8 of Pfizer's main brief) was made after an affidavit had been filed by a Bristol scientist in connection with the Heinemann application stating that tetracycline salts (such as tetracycline hydrochloride) had unexpected qualities over the free base, tetracycline, and therefore was patentably distinct. There is not one shred of evidence in the record, however, nor any indication whatsoever in any of Lidoff's rulings which would suggest that Lidoff would at any time have held tetracycline to be patentable had he known for sure of the presence of that antibiotic in prior art fermentations.

Pfizer next contends that Lidoff's reconstructed view of the law as to patentability of a chemical compound is contrary to the overwhelming weight of authority.[12] Therefore, according to Pfizer, it is highly improbable that

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[12] Pfizer claims in this connection that there are numerous patent decisions that conflict with the position taken by Lidoff. We note, however, that the Board of Appeals in the Patent Office has subsequently, on at least one occasion, interpreted the law as Lidoff did. In so doing it distinguished decisions cited to us by Pfizer. See *Ex parte Steelmand & Kelly*, 140 U.S.P.Q. 189 (1962), a decision in which Mr. Lidoff participated as a member of the Board. This case and others cited therein hold that for a product to be patentable it must be novel, the only exception being where the claimed product possesses a utility that is different in *kind* from the prior-art product, and not merely in purity or degree. In the instant case, although Conover was entitled to claims on his deschlorination process for making tetracycline, he was not entitled to claims on the compound tetracycline if, as Lidoff pointed out, tetracycline had always been present in a mixture already known and used as an antibiotic. Were the rule otherwise, patent monopolies would be extended beyond the 17-year statutory period by successive discoveries of allegedly "new" antibiotic compounds which in reality were always present in known antibiotic products and processes although up until then unidentified.

Lidoff held such a view in 1954. This argument is also rejected. Lidoff's testimony that he considered the mere presence of tetracycline in prior art fermentations sufficient to anticipate tetracycline product claims is fully corroborated by his own written rejection of such claims and is perfectly consistent with Hutz's Remarks. Lidoff testified:

> ". . . In this record, I rejected the product claims then before me on the ground that the product was not novel because of a speculation, based upon another application, a Minieri application. This Minieri application indicated that tetracycline was co-produced in the production of chlortetracycline, or aureomycin. . . . I was able to base a speculation on the disclosure there that tetracycline was co-produced.
>
> "Based on this speculation, I rejected the product claims in this application [Conover] on the ground that the compound was not novel. And I might point out now, to stave off some future questions, that it was my opinion then, that if the compound . . . were not novel—if it existed, a patent could not validly issue. And I was interested in identification of that particular compound in the broths of the reference patents" (TR. 11,496-97).

He stated in his written rejection of the tetracycline product claims:

> "Minieri et al clearly and specifically disclosed that the microorganism used to prepare *tetracycline* belongs to the Duggar, et al., U.S. 2,482,055 species and that 'the characteristics are identical with those exhibited by a known culture of *S. aureofaciens*'. While neither Duggar or Niedercorn may have realized that tetracycline was in fact produced, they did appreciate,

> and disclose that the product was an antibiotic. No invention is involved in the *identification* of the tetracycline and its hydrochloride inherently produced by the reference processes."

And according to Hutz's Remarks, Lidoff had ruled that a "wholly unrecognized occurrence of some ineffective amount of tetracycline in a prior art product" would bar Pfizer's tetracycline product claims.

Pfizer's next argument concerns the failure of counsel supporting the complaint to call another patent examiner as a witness. Lidoff testified that at the time he was examining the Conover application he had no experience in the fermentation field; that applications dealing with fermentation processes were handled in another division (Division 63) by another examiner, a Mrs. Wendt.[13] He further testified that it was standard Patent Office procedure at the time for an examiner who was unfamiliar with the subject matter of an application to rely on informal memoranda, known as patentability reports, prepared by an experienced examiner, and that his rejections of tetracycline process claims were based on memoranda written by Mrs. Wendt.[14] Since it appears that Mrs. Wendt was available as a witness during the trial of this case, Pfizer contends that it may be inferred from complaint counsel's failure to call her that her testimony would have been damaging to the Commission's case. Pfizer's counsel further state that they "did not know of Mrs. Wendt's significant role" until the hearing on remand

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[13] Lidoff's division, Division 6, was assigned the Conover application because under Patent Office procedures at the time, applications such as Conover's, which contained product claims, were assigned to Division 6 (Tr. 9460).

[14] Lidoff testified, however, that no complications arose from this fact (Tr. 11,544). He alone made the decision to apply the doctrine of inherent production to Conover's *product* claims.

and claim therefore that they were under no obligation to call her.

We note first of all that the statement by Pfizer's counsel that they did not know of Mrs. Wendt's involvement in this matter until the remand hearing is untrue. The record shows that on December 2, 1959, Dr. Herbert W. Taylor testified at length concerning the patentability report procedure and as to the connection between Division 6 (Mr. Lidoff's division) and Division 63 (Mrs. Wendt's division). After he mentioned Mrs. Wendt by name, the following colloquy took place between Bristol's counsel and Dr. Taylor: (Tr. 9462)

> Q. Who was Mrs. Wendt—A. The examiner in Division 63 who handled all of these other applications that Bristol filed that went to 63. I was told by her that she'd written the section of Lidoff's decision on motions which we have focused our attention on, that is the inherent production rejection.
>
> Q. You mean the decision of October 14, 1954, in the second interference proceeding? A. I do.

Secondly, we note that Pfizer's argument ignores other evidence of record which completely rebuts any inference unfavorable to the complaint which may possibly be created by complaint counsel's failure to call Mrs. Wendt. The record shows, in this connection, that even after the Conover patent had been granted, Mrs. Wendt rejected a Pfizer application for a patent on a process for making tetracycline (Tanner, et al.). And the reason given by Mrs. Wendt for rejecting this application was coproduction of tetracycline by prior art processes. In a rejection dated October 4, 1956, Mrs. Wendt specifically stated "Claims 1 to 4 are again rejected as lacking invention over each of Duggar and Niedercorn, of record, for reasons set forth in the record.... The processes of patentees [Duggar and

Niedercorn] produced tetracycline as well as chlortetracycline, as evidenced by each of Bird and Martin [references cited by Mrs. Wendt]. It is immaterial whether or not this concomitant production was recognized or not as note *Allen et al.*, v. *Coe*..."[15] The record further shows that Mrs. Wendt again rejected the Tanner application on April 23, 1957, and again on June 6, 1958, specifically holding that "All the claims are again rejected as lacking invention over each of Duggar, Niedercorn of record, for reasons fully dismissed [sic] therein and Minieri, newly cited, who discloses the production of tetracycline by members of the same genus as that employed by applicant" (CX 921).

In view of the above rejections by Mrs. Wendt and her insistence that tetracycline was inherently produced by Duggar and Niedercorn despite Pfizer's "proof" in the Conover matter (which was cited to her) that it was not, we do not believe that Mrs. Wendt's testimony would have been favorable to Pfizer had she been called as a witness.

Pfizer also argues that the record is "crystal clear that Lidoff was thoroughly acquainted with the phenomenon of tetracycline coproduction at the time of the interviews with Hutz and Murphy" and that this evidence contradicts Lidoff's testimony that he did not believe that he then knew of "any coproduction". In support of this argument Pfizer refers to statements in various patent applications which disclosed coproduction of tetracycline and Aureomycin and to certain of Lidoff's rulings rejecting tetracycline process applications on the basis of his speculation that tetracycline was coproduced by the Duggar and Niedercorn processes. The short answer to this argument is that

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[15] (CX 921) One of the references cited by Mrs. Wendt, *Bird, et al., Antibiotics and Chemotherapy*, dated August 7, 1954 (CX 896) described a procedure for separating tetracycline, chlortetracycline, and oxytetracycline by means of paper chromatography.

Lidoff did not testify that he was unaware of "any coproduction". He testified only that he was unaware that tetracycline was coproduced by prior art processes, i.e., by Duggar or Niedercorn. Lidoff was, of course, informed by applications, such as Minieri, which were before him at the time, that the processes disclosed therein produced tetracycline concomitantly with Aureomycin. But these applications covered *new* processes utilizing *newly* developed strains of *S. aureofaciens* or conditions of fermentation which were different from those disclosed in Duggar or Niedercorn. It was on the basis of the information contained in these applications that Lidoff speculated that tetracycline was coproduced by the *prior art* processes. And in Lidoff's view coproduction of tetracycline would anticipate Conover's claims only if it occurred in the prior art.

The significance of coproduction of tetracycline by prior art processes, as distinguished from coproduction by later developed processes, is pointed up most clearly in the following arguments made to Lidoff by Hutz:

> "It was pointed out [at the last interview] to the Assistant Examiner that there is no reasonable basis for his speculation as to the coproduction of tetracycline in the prior art processes . . . [T]here are no statements whatever in the Minieri, et al. application to the effect that most strains of *Streptomyces aureofaciens* are capable of producing tetracycline under previously known fermentation conditions . . . Minieri et al. themselves, in their brief on their motion to add fermentation counts in the interference . . . have stated that tetracycline could previously be produced only by deschlorination, and that there is no evidence of inherent production by the prior art processes" (CX 4, pp. 34-35).

We note that in the above argument Hutz told Lidoff that the Minieri brief stated that "there is no evidence of inherent production by the prior art processes." Pfizer's counsel now argues to the Commission that the same Minieri brief contains "positive proof" of coproduction that Lidoff could have used to reject Pfizer's claims if he was interested in the coproduction of useless amounts of tetracycline. In this instance, however, we agree with Hutz. The Minieri brief did not inform Lidoff of coproduction in the prior art.

Another aspect of this argument which must be noted concerns Pfizer's counsel's reliance on the following statement by Lidoff in his rejection of the Bogert et al. application on November 2, 1954, as proof of Lidoff's knowledge of coproduction:

> "Claims 1 to 6 are rejected as being unpatentable over Winterbottom et al. who treats crude chlortetracycline (Aureomycin) compounds produced by the process of the Duggar patent which must, inherently, include some tetracycline, . . . Since tetracycline would be an 'impurity' in the crude chlortetracycline employed, applicants process would inherently [be] performed . . ."

According to Pfizer this statement shows that Lidoff believed that tetracycline was an impurity in the prior art and it further argues that he was correct in this belief. Yet the record shows that Pfizer's officials had furnished Lidoff with information which caused him to change his mind. Subsequent to the submission of affidavits in the Conover application, the following representation was made to Lidoff in a document signed by Connolly and Hutz:

> "It is believed that the Patent Office is now aware of the fact that this 'inherent' production of tetracycline by the Duggar process is not in fact true. Tetracycline

> would most emphatically not be an 'impurity' in the prior art methods, as the Examiner believed at the time of his last Office Action herein, . . ." (CX 13, p. 16)

Under the circumstances, it is obvious that the Pfizer attorneys construed the affidavits as proof that no identifiable tetracycline was coproduced in the prior art.

Pfizer next contends that even if it be assumed that Lidoff was interested in the coproduction of any identifiable tetracycline, he was careless in reviewing Hutz's Remarks and ignorant of fermentation processes; and that as a result he misled Pfizer's representatives regarding the information he wanted. In the first place, we find no basis in the record for the charge that Lidoff was careless. As we have noted before, Pfizer's summary of what transpired at the conferences was sufficiently in accord with Lidoff's position that he had no reason to question the written account of these conferences. Further, even though Lidoff, as he testified, was unfamiliar with fermentation processes this cannot condone Pfizer's withholding of relevant data. On the contrary, in the face of these circumstances, Pfizer's representatives and scientists, being the experts on fermentation processes, were under a still greater duty to be zealous in providing Lidoff with the information they had in their possession.

Aside from these unfounded charges, Pfizer bases the assertion that Lidoff failed to communicate his thoughts on the following portion of his testimony (Tr. 11,601-602):

> "Q. Do you consider that Mr. Hutz and Mr. Murphy gave you what they understood you were interested in? A. Do you want me to answer that question?
>
> Q. Yes. A. As far as I know, I assumed that they gave me what I had asked for, but they gave me what they understood, yes. They did not give me—well, I

retract that. I don't know what they gave me with relation to what I actually wanted.

Q. But they gave you what they understood you wanted. A. Apparently.

Q. Isn't that so? A. Apparently so, I have nc reason to believe otherwise."

Pfizer construes this testimony as an acknowledgement by Lidoff that Hutz and Murphy probably misunderstood him. We do not agree. The portion of the testimony immediately preceding the excerpt that Pfizer relies on, reads as follows (Tr. 11,601):

"A. I have no control of what they understod by my words. Whatever they understood, my feeling was that this patent should not issue if the compounds were not novel. And this is the only thing that I was basing my stand on.

What they understood by my words I do not know and have no influence on at all."

Obviously, Lidoff realized that he could not testify as to what knowledge Pfizer's representatives possessed. His testimony cannot be invoked as support of Pfizer's professed innocence. It is a question for this tribunal to determine whether Pfizer has acted in accordance with the principles of utmost candor and good faith.

From our review of the record we find that Lidoff did communicate to Pfizer's officials the fact that he was interested in the presence of tetracycline in prior art fermentations. We base this finding on evidence already referred to herein and on the clear showing in the record that prior to the November 29 and December 8 interviews at the Patent Office the basis for Lidoff's rejection of the tetracycline claims was well known to other interested persons. The record discloses beyond question that officials of Upjohn,

Cyanamid, Squibb and Bristol knew that Lidoff had speculated that tetracycline has been inherently produced in the prior art and that the ground of his rejection of the tetracycline claims was lack of novelty. Contemporaneous statements of these officials reveal that they knew that Lidoff was interested solely in the fact of coproduction, that in his view the mere presence of tetracycline in the prior art would anticipate claims for the product.

We also find that even under Pfizer's view that Lidoff was interested solely in quantities of tetracycline that could be recovered by practical recovery procedures (as distinguished from smaller quantities that could be identified only by analytical methods), its representatives were guilty of suppressing material information. In selecting the prior art fermentations for their tests, Pfizer's representatives had a clear choice to make: whether to run a fermentation of Niedercorn Example 1, which Dr. Bogert already knew produced broths having significant antibiotic potency containing 5 percent tetracycline, or whether to test Example 28 which he knew consistently produced broths having little or no antibiotic potency and were useless for determining whether coproduction occurs. They chose the poorer example for their tests and suppressed the facts pertaining to Example 1. Dr. Bogert later testified that he could have recovered tetracycline from a Niedercorn Example 1 broth (CX 34, p. 32). The obligation to deal with the Patent Office in utmost good faith required Pfizer to place this information before Lidoff. Lidoff testified that had he been told of these facts at the November 29 conference, he would not have required any further tests of Pfizer but would have let his previous rejection stand.

Although Hutz and Murphy denied knowledge of the results of the prior October experiments of Tanner and Bogert in which Bogert found clear evidence of coproduc-

tion, nevertheless it was Porter, Pfizer's general counsel, and Murphy who had initiated those prior experiments in an effort to gather data to disprove Lidoff's speculation that coproduction occurred. Also, the record shows that Tanner had conveyed to Murphy some of the relevant data about those experiments, such as the troublesome high level of pH that Tanner encountered in running the Niedercorn Example 28 fermentation (Tr. 4227-29). But even if Hutz and Murphy did not know specifically of Bogert's identification of five percent tetracycline at the time of the first conference with Lidoff on November 29, 1954, the information was clearly available to them by the December 8 conference since they had worked side-by-side with Bogert in the meantime. It is obvious that they were either told of Bogert's discovery of coproduction or he secreted it from them. In either case, the Patent Office was kept in the dark by deliberate withholding on the part of some Pfizer employee or employees.

In addition, material information was suppressed by Pfizer regarding both the extremely low potencies of the test broths (1/20th of those described in the patents) and the fact that during the initial stages of fermentation of one of the broths the pH far exceeded the optimum limits prescribed by the Niedercorn patent. Although the low potencies and the high pH may not have been the fault of Pfizer's scientists it was obviously relevant information and Mr. Lidoff testified that had he known of these facts he would not have considered the tests as duplicating the prior art processes.

In dealing with the Patent Office, applicants can and do, of course, present favorable data to support their claims. But at the same time they can not in good faith withhold conflicting or unfavorable data. The Patent Office, not having testing facilities of its own, must rely

upon the integrity of applicants and their attorneys. They stand to that Office in a confidential relationship and must observe "the highest degree of candor and good faith." *Kingsland* v. *Dorsey*, 338 U.S. 318, 319 (1949). "Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies." *Precision Instrument Manufacturing Co.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806, 818 (1945).

The Commission in its first decision in this matter, without the benefit of the patent examiner's testimony, based its opinion on the finding that Pfizer's actions, at the very least, amounted to "unclean hands", "inequitableness" and "bad faith"—the grounds which strip a patentee of his rights to enjoin infringement of his patent in a court of equity. See *Precision Instrument, supra,* and *Hazel-Atlas Co.* v. *Hartford-Empire Co.*, 322 U.S. 328 (1944). Mr. Lidoff's testimony has fully corroborated that finding, and on the basis of our examination of the entire record we conclude that Pfizer failed to abide by the standards of candor and good faith in procuring its patent, and that this conduct together with the subsequent exploitation of the tetracycline patent constituted a violation of Section 5 of the Federal Trade Commission Act. As a result of this offense, Pfizer has been able to exercise monopoly rights over an important antibiotic, sales of which have exceeded $100 million per year.

We further find, as an alternative ground, that the evidence is clear and convincing that Pfizer committed fraud upon the Patent Office in procuring its patent. Pfizer's subsequent attempt to monopolize the tetracycline market was a violation of Section 2 of the Sherman Act, *Walker Process Equipment, Inc.* v. *Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), and hence of Section 5 of the Federal Trade Commission Act.

Cyanamid's Appeal

As stated above, in November 1953, Lidoff asked Harvey Edelblute, Cyanamid's patent counsel, whether strains of *S. aureofaciens* used by Cyanamid in producing Aureomycin may have produced tetracycline. Edelblute assured Lidoff in December 1953 that Cyanamid had never produced any tetracycline "inadvertently or otherwise" in prior Aureomycin operations. Subsequently, however, Cyanamid determined the presence of tetracycline in Aureomycin products but failed to divulge this information to the Patent Office.

The examiner found that not only did Edelblute fail to inform Lidoff of the true facts when they became known to him but that "while the second interference was in progress, Cyanamid's representative, in papers filed with the Patent Office, continued to deny any inherent production." Mr. Lipscomb further held that had Cyanamid advised the patent examiner during the second interference that the Duggar and Niedercorn fermentations contained tetracycline and that commercial Aureomycin contained tetracycline, the Pfizer-Conover patent application would have been barred because (1) tetracycline was produced under the processes of prior patents and (2) tetracycline was available to the public prior to the filing of the Conover application.

Cyanamid argues that Edelblute did not know the real basis for Lidoff's rejection of the tetracycline claims, that Edelblute had no knowledge of coproduction of tetracycline in the manufacture of Aureomycin, and that even if Edelblute knew that tetracycline was coproduced with Aureomycin, such information would have had no bearing whatsoever on the issue of whether tetracycline was patentable under Lidoff's view of the law.[16]

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[16] We are also asked to dismiss the complaint as to Cyanamid on the ground of mootness since its principal Aureomycin patent, i.e.,

None of these contentions has merit. As to Edelblute's understanding of Lidoff's view of patentability and hence his interest in coproduction of tetracycline, Cyanamid contends that even if Edelblute "had known that actually small amounts of tetracycline were produced in making Aureomycin he still would not have thought Lidoff would regard this as barring patentability to tetracycline". According to Cyanmid, Edelblute thought that "Lidoff wanted to know whether substantial amounts of tetracycline were produced by prior art processes, or were present in Aureomycin, to have the utility of tetracycline unmixed with chlortetracycline". In making this argument Cyanamid completely ignores evidence which establishes beyond any reasonable doubt that Edelblute knew that Lidoff regarded the mere presence of tetracycline in the prior art product as sufficient to bar patentability to tetracycline. This evidence includes a memorandum written by Edelblute on October 27, 1954, wherein he commented on Lidoff's October 14 ruling that tetracycline was unpatentable because of inherent production. Referring to this ruling by Lidoff, Edelblute stated: "... the Examiner is in error as a matter of law. There are many decisions, some recent, which hold that the mere presence of a substance as an impurity in an old material does not negative patentability to that substance when its presence was unsuspected, unknown, and not utilized". (RACX 878C) It is obvious from this state-

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the Duggar patent, expired in 1966. The Niedercorn patent, however, which was issued as an "improvement" patent on the Duggar patented process, will not expire until 1969; and under the Commission's original order in this case Cyanamid was required to license not only the Duggar patent but also the Niedercorn patent. We have no assurance that Cyanamid might not seek to employ the Niedercorn patent in an attempt to enjoin the utilization of tetracycline fermentation processes as this respondent has done with respect to the Duggar patent. Furthermore, the disclosure of certain technological know-how required by the Commission's original order has not been rendered moot by the expiration of the Duggar patent.

ment that Edelblute did not believe that Lidoff was interested only in whether substantial amounts of tetracycline were coproduced.

The record also discloses that Edelblute was informed prior to the dissolution of the second interference that tetracycline was coproduced with Aureomycin. On February 25, 1954, Dr. Nestor Bohonos, the Cyanamid Director of Mycology Research, sent the following memorandum on the subject of "Old Aureomycin Samples for Chromatographic Study" to Dr. J. H. Williams, Cyanamid's Director of Chemical and Biological Research, Lederle Laboratories Division:

> "In Mr. Martin's memorandum of January 22 to Doctor Phelps on this subject, he showed there were four (4) samples which contained 1 to 6% tetracycline.
>
> "At that time Mr. Martin did not have the dates of preparation of these samples. Mr. Wilhelm has gone back into his research books and reports that these were prepared during the month of March in 1948" (CX 111B).

It appears from the face of this memorandum that copies thereof were sent to various Cyanamid officials, including Edelblute. Also written on the memorandum were the words, "All copies were ret'd & destroyed."

With respect to Cyanamid's argument that information concerning the coproduction of tetracycline in the manufacture of Aureomycin would have been of no interest to Lidoff, the record shows that one of the principal arguments made to Lidoff by Pfizer in support of its position that tetracycline was not coproduced by the Duggar and Niedercorn processes was that Cyanamid "who manufactured literally tons of chlortetracycline (Aureomycin) ... failed to discover any tetracycline in such large-scale manu-

facture, although it devoted extensive research to the recovery, purification and properties of its patented antibiotic".

Not only was the information in question relevant to the issue of patentability under Lidoff's view of the law but Edelblute, by Cyanamid's own admission, knew it was false when he reviewed the Conover file in January 1955. Edelblute nevertheless characterized Pfizer's prosecution of the Conover application as "straight-forward" and could see no evidence of "falsification of facts" (RACX 880).

Cyanamid argues that Lidoff was never asked to testify as to whether or not he relied on any of Edelblute's statements when he allowed Pfizer's patent application. Lidoff did testify, however, that had Cyanamid disclosed the fact that tetracycline was present in Aureomycin, he would have used the information in rejecting Pfizer's application on the additional ground that tetracycline was part of a product that had been in public use and sale. See 35 U.S.C. 102(a) and (b). Of course, as Lidoff explained, in order to use such information against Pfizer, under Patent Office rules the information had to be in a form accessible to Pfizer. Disclosure in connection with the Minieri application at the time that Edelblute was informed of the fact of coproduction in February 1954 would have made the information available to Pfizer during the second interference and would have allowed Lidoff to use the information in rejecting Pfizer's claims.

The only remaining question is whether Cyanamid was under a duty to make such disclosure in Minieri. We find that Cyanamid was, since it was pressing for both tetracycline product and process claims in Minieri and knew that Lidoff believed that coproduction was relevant to the validity of such claims. Cyanamid also knew that Lidoff had been incorrectly informed by Edelblute that coproduction did not occur.

Edelblute himself apparently realized that he was obliged to correct the record in the Minieri application

because later he did file a paper in Minieri in which he stated "Reinvestigation of retention samples of commercial Aureomycin produced by applicant's assignee [Cyanamid] by the Duggar and Niedercorn processes showed that these materials contained amounts of tetracycline ranging from 1 to 2½ percent of tetracycline as against chlortetracycline of these products" (CX 8, p. 82). Conveniently for Pfizer and Cyanamid, however, the disclosure was not made until after the Conover patent had issued to Pfizer. At that point it was too late for the Patent Office to act since once a patent is issued the Office has no authority to recall it.

In sum, the evidence is clear and convincing that Cyanamid deliberately withheld from the Patent Office information which it knew or had reason to believe was relevant to the validity of Pfizer's application for a patent on tetracycline. Cyanamid pursued this course of action with knowledge that it was assured a license in the event a patent on tetracycline issued to Pfizer, and that its position as a leading producer of broad-spectrum antibiotics would be safeguarded because Pfizer had announced its intention that Cynamid would be the *sole* licensee under any patent that issued. Cyanamid's vital interest in seeing a patent on tetracycline issue—preferably to itself, or at least to Pfizer—is vividly illustrated by a statement made by Edelblute to the Patent Office. In urging an early dissolution of the second interference, even though the result might be immediate issuance of a patent to Pfizer, Edelblute explained that Cyanamid would "rather pay royalties to a bona fide patentee than see the pharmaceutical business in which it has a major interest ruined by irresponsible price cutting" (CX 12, p. 115). Although Bristol, Squibb, and Upjohn were eventually able to force their way into the licensing arrangement by threatening to contest the validity of the Conover patent, Cyanamid continued to outsell all others by virtue of the lead time it had gained

in establishing "Achromycin" as the brand name for its tetracycline product.

Conclusions as to the Patent Aspect of the Case

After considering the appeals of respondents Pfizer and Cynamid from Hearing Examiner Lipscomb's initial decision and after reexamination of the entire record in this proceeding, the Commission has determined that the hearing examiner's findings and conclusions as supplemented by this opinion, should be adopted and the appeals denied. Also adopted are findings 1 through 18 and 27 through 29 entered by the Commission on August 8, 1963. Allegations in the complaint, other than those dealt with specifically in the opinion, are dismissed in accordance with the reasoning set forth in the Commission's opinion of August 8, 1963.

The Price-Fixing Charge

In its first decision, the Commission found that respondents had unlawfully agreed to hold the price of tetracycline at the same level as that maintained for the other so-called broad-spectrum antibiotics since 1951. The Commission entered an order on August 8, 1963, requiring respondents to cease and desist from future price fixing and directed them to establish, independently, new prices for their respective tetracycline products.

Subsequent to the Commission's order of December 17, 1963, which directed Pfizer and Cyanamid to license any qualified applicant under their respective patents for the manufacture or sale of tetracycline, new firms entered the field, although not licensed by Pfizer and Cyanamid. *American Cyanamid Company* v. *Federal Trade Commission,* 363 F.2d 757, 817; *McKesson & Robbins, Inc.* v. *Chas. Pfizer & Co., Inc. and American Cyanamid Co.*, 235 F. Supp. 743 (E.D. Pa. 1964). And while the evidence in the record is

limited to the period prior to July 28, 1958, current reports indicate that the price of tetracycline has declined substantially.

Pfizer represents in its brief that bid prices to hospitals have moved downward to levels of less than one-fourth of the 1958 bid prices and that list prices in the prescription market have also fallen. According to this respondent, the price to the retailer of one bottle of 100 capsules (250 mg.), which the record shows was $30.60 in 1958, is now listed by Cyanamid at $11.22, and other competitors of Pfizer sell at even lower "effective" prices. In the face of these developments, it is not unreasonable to assume that prices will tend to be still more competitive once the Commission's licensing order goes into effect.

Mindful that the goal of its order is to remove unlawful restraints and foster future competitive conditions rather than punish for past conduct, two of the four participating members of the Commission (Commissioners Reilly and Elman) believe that the public interest will be adequately served by compulsory licensing and by continued close scrutiny of Pfizer's and Cyanamid's readiness to license others to make and sell tetracycline. In the view of these members, it is now unnecessary to decide whether the uniformity of prices in the 1950's was the result of a price fixing conspiracy as contended by complaint counsel or the product of conscious parallelism as respondents seem to suggest. On the other hand, the other two participating members of the Commission (Commissioners MacIntyre and Jones) believe that the evidence of record amply substantiates the allegations in the complaint relating to price fixing. In the view of these two members, the Commission should adhere to and renew the findings of fact and conclusions of law, and issue the order to cease and desist, relating to the price fixing phase of the case, which were contained in the Commission's previous decision of August

8, 1963. Since there is not a majority of the participating Commissioners favoring such action, however, the portion of the complaint which charges respondents with fixing prices must be dismissed.

The Order

In its original order of December 17, 1963, in this matter, the Commission directed Pfizer to license its Conover patent and so remove the fetters on the manufacture and sale of tetracycline by qualified domestic firms provided they pay Pfizer a 2½ percent royalty on their "net sales". The order included a similar provision with respect to Cyanamid, requiring that respondent to license two Aureomycin patents, i.e., Duggar and Niedercorn, in the event a licensee sought to use Aureomycin or patented Aureomycin processes in the manufacture of tetracycline. Both companies were to provide certain technological information to licensees.

Complaint counsel urge us to eliminate from the new order, which is being issued together with our opinion, the provision calling for the payment of royalties. The asserted basis for this request is the fraud committed by Pfizer and Cyanamid before the Patent Office. But we see no reason to depart from the Commission's first order in this respect. In the opinion accompanying that order, which we adopt, the Commission viewed the proceeding as "antitrust" in nature, and the goal of the order was to eliminate the patent barrier which blocked entry into the tetracycline market, thus prying open the market to newcomers. As the Commission found in its first opinion, a royalty-bearing licensing arrangement may suffice as a means to create and maintain competition in the tetracycline market. Should the provision for a royalty ever become an impediment to effective competition, we can al-

ways reopen the matter and eliminate the royalty or modify the rate as changed conditions may require.

We have no doubt that, where the circumstances justify such relief, the Commission has the authority to require royalty-free licensing. See Note, *Improperly Procured Patents: FTC Jurisdiction and Remedial Power,* 77 Harv. L. Rev. 1505, 1517-19 (1964). Indeed, were this to be considered a *de novo* question in this case, we might well agree with the dissenting Commissioner on the desirability of such a provision here, particularly on the basis of the evidence adduced at the hearing on remand. But, in view of the history of this litigation and particularly in light of the matters settled in the opinion of the Court of Appeals, we think it would be a serious mistake to inject so controversial a new issue into the case at this stage, delaying and perhaps jeopardizing its ultimate disposition.

September 29, 1967

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	
AMERICAN CYANAMID COMPANY, *a corporation;*	
BRISTOL-MYERS COMPANY, *a corporation;*	
BRISTOL LABORATORIES, INC. *a corporation;*	DOCKET No. 7211
CHAS. PFIZER & CO., INC. *a corporation;*	
OLIN MATHIESON CHEMICAL CORPORATION *a corporation; and*	
THE UPJOHN COMPANY, *a corporation.*	

DISSENTING STATEMENT OF COMMISSIONER JONES

In this decision on remand, the Commission has found unanimously that the tetracycline patent issued to Pfizer was procured by fraud on the part of Pfizer and by delib-

erate misrepresentation and withholding of essential and relevant data relating to the patentability of tetracycline on the part of both Pfizer and Cyanamid. The Commission concluded that Pfizer's conduct (which Cyanamid deliberately assisted) "in procuring its patent . . . together with the subsequent exploitation of the tetracycline patent constituted a violation of Section 5 of the Federal Trade Commission Act." Thus the Commission's opinion makes plain that it is the procurement of the patent which is the gravamen of the wrong committed by respondents here followed by the monopolization conduct which that wrongfully procured patent permitted.

I join in the Commission's opinion on the liability of these respondents as respects the wrongful procurement of the patent. I vigorously dissent from that portion of the order entered here by the Commission which expressly permits these respondents to collect royalties under the patents which the Commission found were wrongfully procured and exploited by them.[1] There is absolutely no basis either in logic, reason, equity, fact, or law for this decision on the part of the majority.

The Commission defends its action in this respect by pointing to the fact that the order is designed "to eliminate the patent barrier which blocked entry into the tetracycline

[1] The Commission's order directs compulsory licensing of Pfizer's tetracycline patent and also of Cyanamid's Niedercorn patent to the extent that it is used for the production of tetracycline. The Commission's theory, with which I am in complete agreement, is that both these patents are involved in the production of tetracycline. Cyanamid's deliberate withholding of information from the Patent Office with respect to the validity of Pfizer's application for a patent on tetracycline amply justifies the need for the same relief with respect to its patent to the extent that it too constitutes a barrier to the manufacture of tetracycline as the Commission ordered with respect to Pfizer's patent. It is in this sense that I refer in this dissent to these patents conjointly in the plural and describe them as "wrongfully procured and exploited" by respondents.

market thus prying open the market", that a royalty-bearing licensing arrangement "constitutes a fair means to create and maintain competition in the market" and thus accomplishes this objective. I do not agree that the objectives of antitrust orders are so narrowly confined. Clearly the objective of a Federal Trade Commission proceeding charging respondents with engaging in unfair methods of competition whose effect was to eliminate competition in the sale of tetracycline must be to restore the competition which respondents' conduct has eliminated. Removing barriers to entry in a market achieves only one aspect of this objective. If the new entrants come into the market with one hand tied behind their backs, the mere opening of the market to them is a vain and futile gesture. The importance of licensing fees in "limiting or inhibiting the growth of competition" was pointed out by the Court in *United States* v. *General Electric*, 115 F. Supp. 835, 844 (D.N.J. 1953).

Pfizer stated in its brief that price competition is today of great importance in the tetracycline market and that they expect that it will greatly intensify after the Commission's licensing order goes into effect (Pfizer's Answering Brief Opposing Royalty-Free Licensing, pp. 8-9). Thus Pfizer admits that the major competition in the tetracycline market in the future will be price competition. Indeed the two Commissioners who refused to find that a price fixing order was necessary here did so on the very ground that substantial price competition had been introduced into this market and that, therefore, no price fixing order was necessary in this case. If these assumptions with respect to price competition are valid, then the majority's order permitting respondents to collect 2½% royalties from their competitors under patents which this Commission unanimously finds were wrongfully procured and wrongfully exploited confers on these respondents what

could amount to a decisive competitive edge price wise over all of their competitors. Under the Commission's order these competitors of respondents who have been wrongfully excluded from the market all these years must now come to respondents for a license for which they must pay a substantial royalty and thus the order in essence permits respondents to maintain competitive advantages unlawfully achieved (the very monopolistic conduct which this Commission has just found to be a violation of Section 5).

I cannot agree that this provision in the majority's order requiring respondents' competitors to pay tribute under patents which were wrongfully procured and exploited "constitutes a fair means to create and maintain competition in the market."

Nor do I read any of the case law on this point as precluding either the Commission or a court from prohibiting a respondent from collecting license fees under the circumstances of the facts which we have found in this case.[1] Indeed the Supreme Court in its decision in *United States* v. *National Lead Co.*, 332 U.S. 319, 349 (1947) expressly contemplated the propriety of such ruling in the proper circumstances when it concluded in that case that "On the facts before us, neither the issuance of such licenses on a royalty-free basis nor the issuance of a permanent injunction prohibiting the patentees and licensees from enforcing those patents has been shown to be necessary in order to

[1] The Sixth Circuit in its opinion on appeal in this case (*American Cyanamid Company* v. *F.T.C.*, 363 F.2d 757, 772 (1966)) stated that it was not holding that the Commission could order compulsory royalty-free licensing. I do not believe that this statement can be read as respondents would have us read it as laying down a guideline or establishing the case law for our decision. We must interpret the Sixth Circuit's opinion in terms of the issues before the Court and in the light of the applicable case law on the point laid down by the Supreme Court.

enforce effectively the Antitrust Act".[2] In *United States* v. *General Electric,* 115 F. Supp. 835, 844 (D.N.J. 1953) the Court did in fact sustain the propriety of precisely this type of relief because the importance of price competition and the narrow profit margins prevailing in the lamp industry made it essential to deprive GE of the competitive advantage which collection of the licensing fees would confer on it.

To me the only relief which can be effective and which carries any hope of opening up this market to genuine fair competition and undo the harm to competition which these respondents' conduct has engendered is to enjoin their collection of royalties under these patents in view of the circumstances of their issuance and respondents' exploitation of them. Such an injunction is not an adjudication of the ultimate patentability of tetracycline nor does it operate as a forfeiture of either patent. It simply effectuates the purport of the Commission's decision to the effect that the tetracycline patent, as well as Cyanamid's Neidercorn patent when used to make tetracycline, cannot be exploited because of the wrongful conduct of respondents in procuring the tetracycline patent. Interested parties are left to whatever remedies are available to them, either to seek cancellation of the tetracycline patent or if possible, to perfect the issuance of the tetracycline patent on the basis of a

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[2] The Supreme Court's opinion in *Hartford Empire Co.* v. *United States,* 323 U.S. 386 (1945) furnishes no support for respondents' arguments to the contrary. There, the illegal conduct with which the Court was concerned involved patent pooling and allocation of markets and did not embrace the type of fraud and misrepresentation vis-a-vis the Patent Office in procuring the patent which is the sole basis for the wrong found here. The Supreme Court stated expressly that ". . . if, as we must assume on this record, a defendant owns valid patents, it is difficult to say that, however much in the past such defendant has abused the rights thereby conferred it must now dedicate them to the public" (p. 415).

full disclosure of all relevant facts. In the latter event, this order could be reopened and modified if it could be shown that any of its terms were no longer warranted under the circumstances.

September 29, 1967

Second Opinion of Court of Appeals, 401 F.2d 574

Nos. 18336-37

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

CHARLES PFIZER & Co., INC., *Petitioner,* v. FEDERAL TRADE COMMISSION, *Respondent.*	PETITION to review and set aside an Order of The Federal Trade Commission.
AMERICAN CYANAMID COMPANY, *Petitioner,* v. FEDERAL TRADE COMMISSION, *Respondent.*	

Decided September 30, 1968.

Before: O'SULLIVAN, PHILLIPS and CELEBREZZE, Circuit Judges.

PHILLIPS, Circuit Judge. These consolidated cases involving the "wonder drug" tetracycline are before this Court a second time. In our earlier opinion, reported at 363 F.2d 757, this Court vacated the decision and order of the Commission and remanded the entire proceeding for a de novo hearing without the participation of the Chairman, who was held to be disqualified to sit in this case. Upon remand we directed that the Commission consider

any evidence previously taken and additional admissible and relevant evidence on any issues raised by the complaint. Any party was authorized to require the presence of any previously sworn witness for additional testimony either on direct or cross-examination.

Issues Previously Decided by this Court

For the assistance of the Commission on remand this Court passed upon two additional questions which were presented by the petitions for review at the former hearing:

(a) That, assuming the facts as found by the Commission to be supported by substantial evidence, the Commission had jurisdiction to require as a remedy the compulsory licensing of the tetracycline and aureomycin patents on a reasonable royalty basis; and

(b) That the record considered as a whole did not contain substantial evidence to support the decision of the Commission that the tetracycline patent was issued as a result of misrepresentations to the Patent Office and improper conduct on the part of Pfizer and Cyanamid.

In our former opinion this Court reached no decision on the issue of whether the petitioners fixed and maintained the price of tetracycline in sustantial markets through a price fixing conspiracy.

Proceedings on Remand

Upon remand the Commission reopened the proceeding and remanded it to the "Chief Hearing Examiner for an assignment to an examiner to begin expeditious hearings." The remand proceeding was assigned to Hearing Examiner Abner E. Lipscomb.[1]

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[1] Robert L. Piper, the hearing examiner who originally heard the case and wrote the initial decision, was no longer in the employ of the Commission.

In its remand order the Commission specified that it was for the sole and limited purpose of receiving the testimony of Patent Examiner H. J. Lidoff[2] and of any other witness who had testified previously, with respect to "the issue as to whether Pfizer and Cyanamid made misrepresentations to the Patent Office and withheld essential information, thereby deceiving Lidoff into granting a patent which otherwise never would have been approved."

In addition to the testimony of Examiner Lidoff, two witnesses for Pfizer testified at the new hearing. In his decision on remand the Hearing Examiner found that representatives of both Pfizer and Cyanamid made false and misleading statements to officials of the Patent Office and suppressed and withheld information, all of which were relevant and material to the consideration of the application by the officials of the Patent Office for a patent on tetracycline. Therefore, said the Hearing Examiner, officials of the Patent Office were misled into granting a patent on tetracycline which otherwise never would have been issued. The Hearing Examiner concluded that the acts and practices of Pfizer and Cyanamid constituted unfair methods of competition in commerce within the intent and meaning of the Federal Trade Commission Act.

With the Chairman not participating, the Commission adopted the findings and conclusions contained in the decision of Hearing Examiner Lipscomb as supplemented by its own opinion.[3]

The price-fixing aspect of the case is no longer before this Court. By an equally divided vote of two to two the Commission dismissed that portion of the complaint charg-

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[2] Lidoff did not testify at the previous hearing.

[3] The Commission also readopted findings 1 through 18 and 27 through 29 contained in its Findings as to the Facts and Conclusions of Law issued August 8, 1963, and Part II of its opinion accompanying the final order issued December 17, 1963.

ing respondents with fixing and maintaining the price of tetracycline through a price-fixing conspiracy.

The Commission entered a final order on September 29, 1967, pertinent parts of which are set forth as Appendix A to this opinion. This order requires that Pfizer grant to any domestic applicant making written request therefor a non-exclusive, non-discriminatory license to make, use and sell tetracycline under all claims of Patent 2,699,054 (Conover patent); and that Cyanamid likewise grant a license under Patent 2,609,329 (Niedercorn "improved" patent for aureomycin).[4] The order provides for collection of royalties of two and one-half per cent under both patents.

Present Issue

The issue now before this Court is whether the findings of fact of the Commission are supported by substantial evidence. We answer this question in the affirmative and affirm and enforce the order of the Commission.

Much of the previous uncertainty in the record is eliminated by the testimony of H. J. Lidoff, the Patent Examiner who handled the Pfizer Conover application which ultimately resulted in the issuance of the tetracycline patent. At the time of the application Lidoff was an Assistant Examiner. Prior to the time when he testified as a witness, he had been promoted to membership on the Board of Patent Appeals. He is a career employee, having served with the Patent Office continuously since 1937.

Lidoff's testimony contradicts the inferences and findings of fact of Hearing Examiner Robert L. Piper in his initial decision and supports the initial findings of the Commission as well as the findings on remand.

The factual issues are discussed in some detail in the former opinion of this Court, 363 F.2d 757. The basic ques-

[4] Cyanamid's earlier aureomycin Patent 2,482,055 (Duggar) expired in 1966.

tion is whether Pfizer and Cyanamid made misrepresentations to Lidoff and withheld essential information from him, thereby deceiving him into granting a patent on tetracycline which otherwise would never have been approved. The testimony of Lidoff, together with the Patent Office records, substantially support the affirmative findings of the Commission to this effect.

Posture of Pfizer and Cyanamid to Obtain a Monopoly on Tetracycline

As pointed out in our earlier opinion, tetracycline has been described as "currently the best selling wonder drug in the United States." The complaint in this proceeding stated that the antibiotics industry is one of dynamic growth, with sales exceeding $330 million per year, and that tetracycline enjoys the largest sale by dollar volume, aggregating more than $100 million in 1957.

At the time the application for a patent on tetracycline was pending before the Patent Office, Pfizer and Cyanamid were in a posture to establish a monopoly in the production and sale of this drug which is of vital and unique importance in the treatment and cure of many diseases and of considerable impact upon the public health.

Penicillin was never patented. Nobody obtained a monopoly on it. Its production and sale proved to be fiercely competitive and profits were marginal.[5]

On September 13, 1949, Cyanamid obtained its patent on aureomycin (Duggar patent No. 2,482,055). On September 2, 1952, Cyanamid obtained an improvement patent on the Duggar process for producing aureomycin (Niedercorn

[5] Cyanamid's attorney stated in a written memorandum to Lidoff in 1954, during the second interference proceeding, that Cyanamid would rather pay royalties on tetracycline to a bona fide patentee than see the pharmaceutical business in which it has a major interest ruined by irresponsible price cutting.

patent No. 2,609,329). On July 19, 1950, Pfizer obtained a patent on terramycin (Sobin patent No. 2,516,080). As a result of these patents, Cyanamid and Pfizer have had a legal monopoly on the production and sale of aureomycin and terramycin, respectively.

On October 23, 1952, Pfizer filed its Conover application for a patent on tetracycline. This was followed on March 16, 1953, by Cyanamid's Boothe-Morton application for a patent on tetracycline. On October 29, 1953, Lidoff declared an interference for the purpose of determining priority of invention between these two applications.

In the meantime Heyden Chemical Company filed its Minieri application for a patent on tetracycline. On November 4, 1953, Cyanamid made a contract to acquire the Antibiotic Division of Heyden, including the rights to the Minieri patent application.

Thereupon Pfizer and Cyanamid executed a cross-licensing agreement.[6] Under this agreement, and with Heyden's Minieri application now owned by Cyanamid, these two companies were assured of sharing a monopoly on tetracycline if the Patent Office could be persuaded to grant a patent to either of them. Cyanamid then conceded that Pfizer's Conover application had priority in time and withdrew its Boothe-Morton application. This resulted in termination of the first interference on February 9, 1954, and removal of one obstacle from the pathway to obtaining a patent.

Another obstacle was an application filed by Bristol-Myers Company for a patent on tetracycline. As a result of Bristol's application, Lidoff declared a second interference, which continued from March 2, 1954, until October 14, 1954. The proceedings during this interference, its

[6] Negotiations had begun in November 1953. The formal agreement was executed January 11, 1954.

subsequent dissolution and the events following dissolution leading up to the ultimate granting of the patent to Pfizer encompass the issues of fact now before this Court.

Obligation of Parties in Patent Office Proceedings

The Patent Office, not having testing facilities of its own, must rely upon information furnished by applicants and their attorneys. Pfizer and Cyanamid, like all other applicants, stood before the Patent Office in a confidential relationship and owed the obligation of frank and truthful disclosure.

In *Kingsland* v. *Dorsey,* 338 U.S. 318, 319, the Supreme Court quoted with approval the following:

> "By reason of the nature of an application for patent the relationship of attorneys to the Patent Office requires the highest degree of candor and good faith. In its relation to applicants, the Office ... must rely upon their integrity and deal with them in a spirit of trust and confidence...."

In *Precision Instrument Mfg. Co.* v. *Automotive Maintenance Machinery Co.,* 324 U.S. 806, 818, the Court said:

> "Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue.... Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies."

Initial Rejection of Pfizer's Application

In its opinion on remand the Commission found that in its conduct before the Patent Office Pfizer failed to abide by the standards of absolute candor and utmost good faith to which applicants and their attorneys must adhere in procuring a patent. The Commission also found that Cyanamid aided Pfizer in its efforts to secure the patent by deliberately withholding information which it knew or should have known was relevant to the patentability of tetracycline. The Commission concluded that the withholding of information together with the cross-licensing agreement constituted an illegal attempt by Pfizer and Cyanamid to share in an unlawful monopoly which in the light of the subsequent exploitation of the tetracycline patent resulted in a combination in restraint of trade in violation of Section 5 of the Federal Trade Commission Act.

These misrepresentations and the withholding of information related to the question of fact which Lidoff considered to be determinative to the issue of patentability: that is, whether tetracycline is inherently produced under the processes of the two aureomycin patents.

In an earlier ruling on the Minieri application dated September 28, 1953, Lidoff said that "the production of tetracycline as well as varying amounts of aureomycin... would appear to be inherent in the process of Duggar.... There is found no patentable invention in culturing Duggar's mutants under the same conditions and finding that tetracycline as well as [aureomycin] is produced."

On November 14, 1954, Lidoff dissolved the second interference, ruling that tetracycline is not patentable because it appeared to lack novelty. Because of the disclosures of the Minieri application Lidoff ruled that tetracycline is unpatentable because it is produced in the processes of Cyana-

mid's Duggar and Niedercorn patents. His written ruling contained the following language:

> "Duggar and Niedercorn each produce an antibiotic, disclosed as 'Aureomycin' by a fermentation process employing *streptomyces aureofaciens* and mutants thereof. The antibiotic is identified as an antibiotic by assay against bacteria. It appears from the disclosure of Minieri et al (a party to interference No. 86,861 in an application available to all the parties) that tetracycline is *also* produced in such a fermentation process and that larger proportions thereof are produced when the amount of chloride in the fermentation medium is low. . . . Minieri et al clearly and specifically disclose that the micro-organism used to prepare *tetracycline* belongs to the Duggar et al U.S. 2,482,055 species."[7]

Misrepresentations and Withholding of Pertinent Information by Pfizer

On November 29, 1954, Pfizer's patent representatives met with Lidoff at his office concerning the rejection of the application. A written summary of the interview was prepared by Pfizer's representatives and filed with the Patent Office.[8] Representation was made on behalf of Pfizer that there was no reasonable basis for Lidoff's speculation "as to the coproduction of tetracycline in the prior art processes." The written summary recites that Lidoff felt that he was justified in relying upon the disclosure of Minieri "as giving rise to a rebuttable assumption of inherent production." Pfizer's representatives denied that any such prima facie assumption is justified and

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[7] Lidoff's written ruling is quoted in part at 363 F.2d 775, n. 12. He said: "It has long been held that a purer form of an old product is not inventive."

[8] The summary is quoted in part at 363 F.2d 775-76.

asserted that "the available evidence is overwhelming contrary to the Examiner's assumption." Pfizer also argued that Cyanamid, which had manufactured literally tons of aureomycin under its Duggar and Niedercorn patents, had failed to discover *any* tetracycline in its large-scale manufacture, although Cyanamid had devoted extensive research to the recovery, purification and properties of aureomycin. It was argued that the experience of Cyanamid "should conclusively refute the tenuous basis for the Examiner's unwarranted assumption." The summary further states that Lidoff adhered to his position that he would not withdraw his rejection unless the applicant would submit a showing overcoming his speculated basis for rejection.

Pfizer then embarked on a program to convince Lidoff that his finding of inherent coproduction was erroneous.

Pfizer's patent agent previously had issued memoranda to two Pfizer scientists on October 15, 1954, instructing them to conduct work on the question of coproduction of tetracycline, informing them that the work was in connection with the prosecution of the patent application and that the results might be used in preparing affidavits to be filed with the Patent Office.

The Niedercorn patent on aureomycin contained forty-four samples or examples of media. Two broths were prepared by Pfizer scientists in accordance with the specifications set forth in Example 1. These tests showed that approximately five per cent of the total antibiotic activity in the filtered broth consisted of tetracycline. The results of this test were never disclosed to Lidoff, although expert testimony established that tetracycline could have been recovered from Example 1 broths at the time of these tests in October 1954. The Hearing Examiner found that if Pfizer's representatives had disclosed to Lidoff in the conference on November 19, 1954, the results of the tests of

Example No. 1, this would have confirmed Lidoff's conclusion of inherent coproduction and would have ended the matter. No further test would have been specified, and the patent would never have issued. Lidoff testified that if he had been furnished this information concerning Example 1, "I would not have allowed the patent."

Instead Pfizer's representatives suggested that tests be made to determine whether tetracycline could be recovered from Niedercorn Example 28. They did not disclose to Lidoff that earlier tests conducted by Pfizer scientists demonstrated Example 28 broths to be so poor in antibiotic potency that they revealed neither aureomycin nor tetracycline.

The written summary of the interview with Lidoff on November 19, 1954, prepared by Pfizer's representatives, states that Lidoff required evidence that fermentation broths produced "strictly in accordance with the Duggar and Niedercorn disclosures ... do not contain recoverable amounts of tetracycline."

Pfizer conducted its tests on Example 28, which previous experience demonstrated contained no tetracycline, instead of Example No. 1, which produced approximately five per cent of recoverable tetracycline. Lidoff denied that he selected Example 28 and testified: "I was interested in the conditions most likely to produce tetracycline—period." The Hearing Examiner found that, in its tests on one of the two Example 28 specimens, Pfizer did not adhere strictly to the Duggar and Niedercorn disclosures. The Niedercorn patent states that "for maximum growth, it is necessary that the pH of the fermentation medium be controlled within rather narrow limits. Highly effective growths may be obtained within the range of about 5.0 to 8.0. Best results are obtained within the range of approximately 6.4 to 6.7." The Hearing Examiner emphasized that Pfizer's affidavit represented that the entire fermentation was conducted at a pH

of 6.7, whereas the beginning fermentation in one of the examples had a pH at 8.1, and was adjusted downward to 7.1 six and one-half hours later.

Pfizer's representatives failed to disclose to Lidoff the deficiencies in the Example 28 fermentation. Instead the affidavit was drafted to show that the Niedercorn Example 28 test was conducted throughout at the best possible pH for antibiotic growth. The Hearing Examiner further found that notwithstanding the low potency of the Niedercorn Example 28 test broth, Pfizer's representatives misleadingly told Lidoff that this broth was "truly representative" of a Niedercorn Example.

Lidoff testified: "[N]ormally we would expect that the precise conditions of the example would be duplicated to present a proper comparison. Any deviation therefrom without being put in the record would not be a proper presentation of the case. . . ."

"[H]ad it been called to my attention that there was a difference in pH, I would automatically have pointed out that there was not a proper comparison—that comparisons to be proper must be duplicates. . . ."

"[A] test run at 8.1 would not in my opinion be properly representative of an example which in accordance with the specific disclosure of the Niedercorn patent obtained best results at a pH from 6.4 to 7."

Pfizer submitted affidavits to Lidoff, executed by two of its scientists, reporting unsuccessful efforts to recover tetracycline from Example 28 fermentation broths. Lidoff requested still more information in affidavit form as to the possibility of recovering tetracycline. On December 9, 1954, another interview was held between Pfizer's representative and Lidoff and a supplemental affidavit was filed stating: "[I]n fact there was no indication whatever of the presence of tetracycline."

In support of its Bogert application No. 423,247 for a process patent for separating antibiotics Pfizer's representative stated in a written document filed with the Patent Office May 4, 1955:

> "The Examiner points out that the reference treats the products of the Duggar process and he concludes that such products 'inherently contains tetracycline.' It is believed that the Patent Office is aware of the fact that this 'inherent' production of tetracycline by the Duggar process is not in fact true."

It is to be emphasized that at the time of these representations Lidoff was still groping for information. Pfizer already had established coproduction as a *fact* while to Lidoff this remained a matter of *speculation*. The Commission correctly held that it was the obligation of Pfizer to disclose the results of the Example 1 tests and the deficiencies and variations in the Example 28 tests. Under the circumstances Pfizer cannot disclaim this responsibility because Lidoff, who was never informed of the Example 1 tests, did not expressly require use of Example 1 instead of Example 28.

Convinced by Pfizer's representatives that tetracycline was not inherently coproduced in manufacturing aureomycin, Lidoff changed his decision and granted the patent.

We hold that there is substantial evidence to support the Commission's findings that Pfizer suppressed material information relative to the results of the Example 1 tests and to both the extremely low potencies of the Example 28 broth tests and the fact that during the initial stages of fermentation of one of the two tested broths the pH factor exceeded substantially the optimum range prescribed in the Niedercorn patent. We further hold that substantial evidence supports the Commission's conclusion that Pfizer

made misrepresentations of material facts and withheld pertinent information, thereby obtaining a patent on tetracycline which otherwise never would have been issued.

Withholding of Pertinent Information by Cyanamid

During a conference with Cyanamid's patent counsel on November 16, 1953, Lidoff inquired whether strains used by Cyanamid in making aureomycin might have produced tetracycline. The attorney replied that he did not know but would find out and advise Lidoff. Cyanamid's counsel made inquiry and reported to Lidoff that Cyanamid "can unequivocally state that there has not been any tetracycline produced by them, inadvertently or otherwise."

Early in 1954 Cyanamid scientists conducted tests on old samples of aureomycin and found evidence that tetracycline was present. Further tests by Cyanamid scientists confirmed the findings of the prior tests showing coproduction of tetracycline. The record supports the findings of the Hearing Examiner that Cyanamid knew during 1954 that aureomycin contained tetracycline; that analysis of aureomycin fermentation broths on January 20, 1954, showed tetracycline in five of the six samples tested; and that other tests by Cyanamid conclusively confirmed the presence of tetracycline in aureomycin.

On February 25, 1954, the Cyanamid Director of Mycology Research sent out a memorandum to five other Cyanamid scientific personnel and to patent counsel which contained information that the tests of some old samples of aureomycin which had been produced in 1948 showed that they contained one to six percent tetracycline. Cyanamid's patent counsel testified that he did not remember seeing this memorandum until just prior to the Commission hearings in 1959. The Commission found that "coun-

sel had ready access" to the information. Written on the face of this memorandum, which Cyanamid produced from its files in 1958 pursuant to a Commission subpoena, were the words "All copies were ret'd and destroyed." Under the rule of candor and truthfulness required of applicants before the Patent Office, the contents of this memorandum, contradicting Cyanamid's previous representations, should have been revealed to Lidoff. The record is silent as to which Cyanamid official directed that all copies of this highly significant document be returned and destroyed. Accepting as correct the testimony of Cyanamid's patent counsel that he had no recollection of having seen it at that time, responsibility for suppressing the facts shifts to the unknown Cyanamid official who directed that all copies be recalled and destroyed. We agree with the Commission that Cyanamid cannot escape responsibility for these actions.

At no time while Pfizer's patent application was pending or during the interference proceedings did Cyanamid disclose to the Patent Office that its previous representations were erroneous and that tetracycline was present in aureomycin broths. Not until several months after the patent had been issued to Pfizer did Cyanamid advise the Patent Office that, according to "recently" performed tests, tetracycline was found to be coproduced in Duggar-type fermentations and to be present in aureomycin broths.

We agree with the Commission that, because of the strong economic interest in having Pfizer awarded a patent, the fruits of which Cyanamid would share under the cross-licensing agreement, Cyanamid was under the same duty as Pfizer to reveal to the Patent Office information which it had reason to know was material to Pfizer's application.

In summary, Lidoff had made specific inquiry of Cyanamid's patent representative in his effort to reach a correct

decision as to the novelty of tetracycline. The patent attorney gave an unequivocal answer that no tetracycline was produced in Cyanamid's aureomycin commercial operations or in aureomycin broths. This reply was erroneous since tetracycline is and always has been present in aureomycin and is inherently produced in the Duggar and Niedercorn processes. We agree with the Hearing Examiner that "if Cyanamid's patent representative did not know the true facts, he was nevertheless under a duty to know them and under a duty to reveal the truth to the patent examiner."

The Hearing Examiner found that during the summer of 1954, while the second interference was in progress, Cyanamid's representative, in papers filed with the Patent Office, continued to deny any inherent production of tetracycline in aureomycin and that "Cyanamid's knowledge was exactly contrary to its Patent Office statements."

Lidoff testified that if Cyanamid had informed him during the second interference proceedings that aureomycin contained two to four per cent tetracycline, he would have used that as a basis for rejecting all applications claiming the compound tetracycline. He further testified positively that, if Cyanamid had disclosed to him this information, he would have refused to issue the patent and would have held that tetracycline was not novel and was unpatentable because (1) it was produced under the process of prior patents and (2) it was available to the public prior to the filing of Pfizer's application.

Questions Left Unanswered in Former Decision of Commission

Appendix G to our former opinion, 363 F.2d at 817-22, contains numerous examples of contrary inferences drawn from the same evidence by Hearing Examiner Piper in the initial decision and by the Commission in its findings of facts.

At page 363 F.2d 777 are set forth certain material questions which had not been clearly answered in the record then before the Court. Lidoff answered these questions specifically, supporting the Commission's original findings of fact and contradicting the findings of Hearing Examiner Piper in his initial decision.

Pertinent testimony by Lidoff on these questions is set forth in Appendix B to this opinion.

The opinion of the Commission summarizes Lidoff's testimony as follows:

> "Lidoff testified in this connection that as of December 9, 1954, and prior thereto he did not know as a fact that any tetracycline was inherently produced in the Duggar and Niedercorn patent fermentations; that he had speculated on the basis of information contained in the Minieri application that some tetracycline was present in the fermentation broths made pursuant to the teachings of Duggar and Niedercorn; that if tetracycline was inherently produced by these prior art processes and could be identified in the broths he was of the opinion that it lacked novelty and could not be patented; that Hutz and Murphy had vigorously denied at the time that such coproduction occurred; and that the factual question that he was attempting to get answered was whether identifiable tetracycline was or was not present in the broths of the Duggar and Niedercorn patents. Above all, he testified that had he been told by Pfizer that 5% of the antibiotic content of a Niedercorn Example 1 broth was tetracycline he would never have allowed the patent. He further testified that if he had known that commercial Aureomycin contained tetracycline he would have also rejected the Conover application on a different and additional statutory ground."

Admissibility of Lidoff's Testimony

At the former hearing before this Court Pfizer's attorneys stated that Pfizer had urged that Examiner Lidoff be called as a witness by the Commission and had requested an opportunity to interview him, but that their request had been denied. Pfizer complained vigorously of the failure of the Commission to call Lidoff as a witness.

On remand Lidoff was called as a witness and testified at length both on direct and cross-examination. Pfizer now contends that the testimony of this witness is based upon his "reconstructed state of mind," is conjectural and irrelevant and does not constitute admissable evidence.

Lidoff admitted that he did not have an independent personal recollection of all details of his interviews with representatives of Pfizer and Cyanamid. However, his testimony is not based upon mere habit but is grounded upon written records, including documents prepared by him, combined with his familiarity with Patent Office practices, procedures and policies. His written initial rejection of Pfizer's application (see 363 F.2d at 775, n. 12) was more than a "past recollection recorded;" it constituted the very act of rejection. As the author of this document, he is the most authoritative interpreter of its content. We hold this testimony to be admissable. Wigmore on Evidence, §§ 98, 747.

The failure of Lidoff to recall details of interviews conducted by him eleven years earlier is a matter addressing itself to his credibility. Questions of credibility and testimonal weight are issues upon which the courts do not second-guess the Hearing Examiner and the Commission. *Niresk Industries Inc.* v. *Federal Trade Commission,* 278 F.2d 337, 341 (7th Cir.), cert. denied, 364 U.S. 883. The Hearing Examiner, who observed the demeanor of Lidoff while he was testifying, credited his testimony and commented as follows: "Moreover, it has been our observation

that the witness who remembers too well and too clearly may be less credible than the witness who has difficulty in remembering." The Hearing Examiner further said:

> "Mr. Lidoff's testimony, which was presented clearly and unequivocally, explains the numerious factual problems that confronted both the Commission and the Court in their evaluations of the original record; and it supplements and explains clearly proven facts in the record. These facts, combined with Mr. Lidoff's testimony, present clear, convincing and substantial evidence to support and sustain the facts herein found."

Other Contentions of Petitioners

Pfizer continues to assert that Lidoff was interested only in "appreciable" and "recoverable" amounts of tetracycline. Lidoff testified that "[t]he proportion or amount was not significant. The presence was the important thing." As stated by the Hearing Examiner:

> "In fact, the presence of identifiable tetracycline in the fermentation broths produced pursuant to the prior Duggar and Niedercorn patents '. . . was the crux of the whole issue.' Further, Patent Examiner Lidoff made it clear that it was not necessary for a therapeutic product to be coproduced, or for sufficient tetracycline to be present to give tetracycline activity to the mixture, or for commercial amounts of tetracycline to be coproduced. It was only necessary that there be sufficient tetracycline to be identified."

His testimony on this point is supported by his written action of November 24, 1954 (quoted at 363 F.2d 775, n. 12). Pfizer's contention is based upon its interpretation of words written by its own attorneys in the summary of their interview with Lidoff. The Commission adopted a

contrary interpretation of these words, and we find this conclusion to be both reasonable and supported by substantial evidence.

Pfizer further contends that, even if Lidoff was interested in less than "appreciable" or "recoverable" amounts of tetracycline in aureomycin broths, he failed to convey his thoughts to Pfizer's representatives and they were not guilty of any misrepresentations. We hold that substantial evidence supports the Commission's conclusion that the Patent Office records were sufficient to put both Pfizer and Cyanamid's representatives on notice that Lidoff was interested in ascertaining whether any tetracycline was inherently produced in the aureomycin broths, and not ten per cent or other "appreciable" or "recoverable" amounts as now contended.

In any event, under the standards of candor and trust required of applicants before the Patent Office, it was the obligation of both Pfizer and Cyanamid to make a full disclosure, even though they understood Lidoff to be interested only in "appreciable" or "recoverable" percentages.

Pfizer contends that substantial evidence is not the correct yardstick required to sustain the order of the Commission but that the proper standard of proof to support a finding of misrepresentation is "clear, unequivocal and convincing" evidence as in cases of fraud. On the record before us, we could conclude that the Commission's findings of misrepresentation and withholding of material information on the part of both Pfizer and Cyanamid are supported by clear, unequivocal and convincing evidence. In our former opinion, however, this Court held that substantial evidence was the correct standard to be applied in reviewing this order of the Commission. We adhere to that view.

Another argument advanced by Pfizer is that Lidoff's interpretation of patent law as to patentability of an unintentionally produced chemical compound is contrary to the controlling decisions. This is not the question before us. The Commission did not undertake to pass upon the validity of the patent, nor do we. The order of the Commission treats the patent as valid and requires compulsory licensing. The issue here is a violation of Section 5 of the Federal Trade Commission Act, not the validity of a patent. In our former opinion this Court held that, assuming the facts found by the Commission to be supported by substantial evidence, the Commission had jurisdiction to require as a remedy the compulsory licensing of the tetracycline and aureomycin patents on a reasonable royalty basis.

It is further argued by Pfizer that Lidoff vacillated on his views of patentability and therefore his testimony on the standard of patentability which guided him is not credible. To the contrary, the record shows that Lidoff's alleged changes of position were not due to changes in his concept of patent law but to changes in his understanding of the facts. His decision to grant the patent to Pfizer after having denied it initially was caused by the misrepresentations of facts and the withholding of pertinent information which have been discussed in detail in this opinion.

All the other contentions of petitioners have been considered and found to be without merit.

The order of the Commission is affirmed and enforced.

APPENDIX A

EXTRACTS FROM COMMISSION'S FINAL ORDER OF SEPTEMBER 29, 1967

IT IS FURTHER ORDERED that the findings and conclusions contained in the initial decision following remand be, and they hereby are, adopted as the findings and conclusions of the Commission as supplemented by (1) the accompanying opinion of the Commission, (2) findings 1 through 18 and 27 through 29 contained in the Commission's Findings as to the Facts and Conclusions of Law issued August 8, 1963, and (3) Part II of the Commission's Opinion accompanying the Final Order issued December 17, 1963.

IT IS FURTHER ORDERED that respondent Chas. Pfizer & Co., Inc., grant to any domestic applicant making written request therefor, a non-exclusive, non-discriminatory license to make, use, and sell tetracycline under all claims of United States Patent 2,699,054. Said licenses granted hereunder shall be for the full, unexpired term of said patent and shall contain no restriction or limitation, except that such licenses may contain provisions in a form customary in such patent licenses, allowing the licensor to collect royalties of not more than two and one-half (2½) percent of the net sales of tetracycline manufactured or sold under said licenses, providing for the inspection of books and records by independent auditors to determine the correctness of any royalty payment, and providing for the cancellation of the licenses at the option of the licensor upon failure of the licensee to permit such inspection or to pay royalties due and payable. Said licenses shall provide that in the case of the licensor granting or having granted more favorable terms to any other licensee, the licensee under said license shall be entitled to equal treatment; *Provided, however,* that respondent may

require any such applicant to pay upon acceptance of a license an amount not exceeding $2,500 which shall be applied against future royalty payments.

IT IS FURTHER ORDERED that respondent American Cyanamid Company grant to any domestic applicant making written request therefor, a non-exclusive, non-discriminatory license under all claims of United States Patent 2,609,329. Said license granted hereunder shall be for the full, unexpired term of the patent licensed and shall contain no restriction or limitation on the licensee's right to make and sell tetracycline, except that such licenses may contain provisions, in a form customary in such patent licenses, allowing the licensor to collect royalties of not more than two and one-half (2½) percent of the net sales of tetracycline manufactured under said licenses, providing for the inspection of books and records by independent auditors to determine the correctness of any royalty payment, and providing for the cancellation of the licenses at the option of the licensor upon failure of the licensee to permit such inspection or to pay royalties due and payable. Said licenses shall provide that in the case of the licensor granting or having granted more favorable terms to any other licensee, the licensee under said license shall be entitled to equal treatment; *Provided, however,* that respondent may require any such applicant to pay an amount not exceeding $2,500 which shall apply against future royalty payments under any patent or patents licensed hereunder.

IT IS FURTHER ORDERED that respondents Chas. Pfizer & Co., Inc., and American Cyanamid Company each refrain from making any assignment, sale, or other disposition of any of the patents required to be licensed hereunder which would deprive it of the power to issue licenses pursuant to this order unless said respondent requires as a condition of such disposition that the purchaser, assignee, or licensee

shall observe the provisions of this order with respect to such patent and that the purchaser, assignee, or licensee file with the Commission a written undertaking to be bound by such provisions; *Provided, however,* that one or both of said respondents may dedicate any such patent, patents, or a general patent license to the general public in lieu of issuing licenses pursuant to the provision of this order.

IT IS FURTHER ORDERED that respondent American Cyanamid Company furnish to any person licensed under this order, and making written request therefor, whatever technical information and know-how that American Cyanamid Company has in the past furnished Chas. Pfizer & Co., Inc., relating to the manufacture and use of chlortetracycline, said technical information and know-how to include a furnishing of viable *S. aureofaciens* cultures that are identical to or equivalent to any cultures furnished Chas. Pfizer & Co., Inc. The information to be made available hereunder shall be made available without charge other than the expense to respondent of furnishing such information; *Provided, however,* that respondent American Cyanamid Company may require any such licensee to agree to keep said technical information and know-how confidential.

IT IS FURTHER ORDERED that respondent Chas. Pfizer & Co., Inc., furnish to any person licensed under United States Patent 2,699,054 pursuant to this order, and making written request therefor, whatever technical information and know-how that Chas. Pfizer & Co., Inc. has in the past furnished American Cyanamid Company relating to the manufacture of tetracycline by the deschlorination process. The information to be made available hereunder shall be made available without charge other than the expense to respondent of furnishing such information; *Provided however,* that respondent Chas. Pfizer & Co., Inc., may require

any such licensee to agree to keep said technical information and know-how confidential.

IT IS FURTHER ORDERED that respondents American Cyanamid Company and Chas. Pfizer & Co., Inc., shall within sixty (60) days after the effective date of this order file with the Commission a written description of the know-how and technical information required to be furnished under Paragraphs 6 and 7.

IT IS FURTHER ORDERED that that portion f the complaint charging respondents with fixing prices be, and it hereby is, dismissed.

IT IS FURTHER ORDERED that respondents American Cyanamid Company and Chas. Pfizer & Co., Inc., each shall file with the Commission within sixty (60) days after the effective date of this order, a report in writing under oath, signed by each respondent, setting forth in detail the manner and form of its compliance with this order.

By the Commission, Chairman Dixon not participating; and Commissioner Jones dissenting from that portion of the order permitting respondents to collect royalties under the patents.

JOSEPH W. SHEA
Joseph W. Shea,
Secretary.

APPENDIX B

EXCERPTS FROM TESTIMONY OF H. J. LIDOFF

Q. Now, Mr. Lidoff, the Sixth Circuit Court of Appeals, in remanding this proceeding to the Commission, propounded certain questions or inquiries, and I would like to take those up with you at this time, and there will be some repetition of what you have already stated.

Mr. Lidoff, I want to ask you if at the time the notice of allowance was issued in Pfizer's Conover application, and prior thereto, to what extent were you aware of inherent coproduction of tetracycline in aureomycin broths and in the finished product? A. I was not aware of such information, at least in any available form that could be applied in rejecting the application.

Q. The second question of the Court.

In handling applications, including Pfizer's Conover application, for a product patent on tetracycline, were you concerned only with co-production in aureomycin as a finished product, or was your inquiry also directed to co-production in aureomycin fermentation broths? A. Overall I was interested in the prior production in any manner of tetracycline, specifically in this interest the production of tetracycline in conjunction with aureomycin, in view of the references which dealt with, at least ostensibly dealt with the production of aureomycin.

Q. Was the Federal Trade Commission Hearing Examiner that handled this case initially correct or incorrect in his finding that if you had known that old aureomycin contained from two to five per cent tetracycline, you would nevertheless have granted the Pfizer tetracycline patent to Pfizer? A. Well, as pointed out before, while it would have been based on a different portion of the statute, I would

not have allowed the Conover patent had I known that prior commercial aureomycin actually contained tetracycline, noting, of course, that this is a different rejection than the rejection that we have been discussing which I did make.

Q. Which you did what? A. Which I did make. That the rejection in the file is a different rejection than that which would have been raised had this been known as a fact.

Q. Next question of the Sixth Circuit Court of Appeals. Did you consider any amount of co-production of tetracycline in aureomycin under 10 per cent to be immaterial in your handling of the Pfizer application for patent on tetracycline? A. Well, that sentence is a little involved. No, I did not consider that production of any amount under 10 per cent to be immaterial because—

Q. Is that immaterial? A. Immaterial—because the production of any amount regardless of the numerical value would in my opinion have at that time properly supported the rejection. In other words, there is no numerical limitation to the amount of tetracycline produced. The important factor, in my mind, was was any tetracycline produced.

Q. Why did you request tests by Pfizer of Niedercorn Example 28, if you did, rather than requesting tests of other examples among the 44 listed in the Niedercorn patent—and this is the Court's question—at least one of which, Example 1, the Commission found would have disclosed 5 per cent co-production. A. This requires some generalization here.

First of all, a patent examiner does not require tests. A patent examiner makes a rejection and in order to overcome this rejection, an applicant may, if he desires, present so-called tests or comparisons or any other data normally in affidavit form.

It is not the function of the patent examiner either to require tests or to point out specifically what tests should be made. Normally, however, a compromise has to be reached in view of the facilities available to the applicant for making the tests, and none are available to the patent examiner to check the tests. Normally a compromise is reached, and applicants present affidavits, present tests and comparisons, and based upon these an Examiner makes up his mind, realizing that they are not necessarily the best or the ultimate in comparisons and in testing.

It is a question of working out the best possible compromise.

Now, I will say further that an Examiner will, in discussion, attempt to select from tests presented to him, or from data presented to him, if so asked—will attempt to point out the more convincing evidence. However, the selection of the test is normally in the province of the applicant.

Q. Well, did you limit Pfizer to Example 28? A. Definitely no, I would not have. Now, remember, I don't recall precisely—I cannot. But I would not have limited testing to any example. I might have suggested that that looked the most promising, but I would not have limited the test to that example.

Q. Now, this is another question of the Sixth Circuit, and I will read it.

In your handling of the Pfizer Conover application for a patent on tetracycline, were you interested in establishing only that the prior art processes did or did not produce tetracycline in appreciable—and that is in quotes—amounts, making possible its prior recovery as a therapeutic product. A. First of all, I was not—I would not have been interested in recovering a therapeutic product. The claim was directed to a compound per se, not to a

therapeutic product. So that my interest would have been identification of the material tetracycline as present.

However, we run into some semantics here—and I know we will further on, as to recovery of appreciable amounts and so forth—and I might summarize that my interest was in determining whether or not the material tetracycline was present.

However, at that time at least, most methods of identifying and determining the presence of this material would have in the broadest sense been encompassed by the word "recovery". You normally in order to identify something recover it to the extent of at least separating it from some of its impurities. So that while we are bandying words back and forth, the important factor in my view of patentability was that if any identifiable amount of the material were present, a valid patent could not issue, and regardless of what language we ended up using, this is what I was after.

Q. I see.

Was the Federal Trade Commission Hearing Examiner correct in his conclusion that you knew "for more than a year prior to the decision on the second interference" that fermentation broths produced under Duggar and Niedercorn usually contain tetracycline, or was the Federal Trade Commission correct in its conclusion to the contrary? A. The answer is I did not know.

Q. Did you draw a distinction as to the significance of co-production as between product and process applications as found by the FTC Hearing Examiner, or was the Federal Trade Commission correct in reaching its contrary conclusion? A. Simply speaking, I did not make a distinction in my mind between the two. This will probably later demand some explanation as to these office actions dealing with fermentation processes and products. If you wish the explanation now, I can put it into the record.

Q. Well, when you say you did not draw a distinction between the two, you mean between the product application and the fermentation process application. A. Correct.

Q. Was the amount—rather, was the co-production of any tetracycline equally a factor in both these types of application? A. No, not equally. In a product claim, the presence of the tetracycline was a determining issue. In a process claim, the process parameters were the important thing, and the product so produced of less significance. So there is a great distinction as to the weight to be given to this co-production.

Q. Is any—is the co-production of any tetracycline relevant to a product application? A. In my opinion, the production of any tetracycline is the most important factor in an application containing claims to the product tetracycline.

Q. The next question I have concerns the Taylor affidavit which you have earlier answered.

[Lidoff testified that he does not remember seeing Bristol's Taylor affidavit, which was filed six days before the patent was issued, but that "the odds are very greatly against my having seen it."]

The next question I will ask you is a question posed by the Sixth Circuit Court of Appeals as follows.

Would your decision to grant the Pfizer Conover patent have been different if Cyanamid had revealed that it was in error in its prior assurances that there was no co-production of tetracycline in aureomycin, or were you already aware of the fact that aureomycin contained tetracycline? A. A, I was not aware of the fact.

Q. I didn't get that answer. A. A—I was not aware of the fact that aureomycin actually contained tetracycline. And B, as I pointed out before, the availability of this knowledge, the form in which the knowledge was available,

would have been the most important thing. That is to say, it has to be in a publication that could be used. The fact that Cyanamid may have admitted it in a record, in a Cyanamid application, would not have been of significance in the prosecution of the Conover application once it was separated from the interference.

Q. Why? A. Because as I pointed out in the Patent Office information in one application, an application assigned to an assignee, cannot be employed to reject another application—an application of a different assignee. The basis for such rejections are normally publication.

Now, that would have to do with published matter.

Now, in addition to that, we have not separated from that particular question whether this information had to do with aureomycin produced in accordance with Duggar and Niedercorn, and that commercially available. That is, we had to split that also.

Q. Well, now, if Cyanamid had revealed during the second interference proceeding between Cyanamid, Pfizer and Bristol, that it was in error in its prior assurances, that there was no co-production in aureomycin, would your decision to grant the Pfizer Conover patent have been different? A. The answer is yes, and let's break it down into two parts.

If they had admitted during the interference that following Duggar or Niedercorn a broth would be produced which contained tetracycline, then I would have maintained the rejection which we did present based upon the Duggar and Neidercorn application.

If, on the other hand, the admission was that commercial aureomycin previously sold to the public had contained tetracycline, then the rejection would have been a different rejection based on a different section of the statute, but nevertheless would have prevented issuance of the patent.

Q. Does that include the Conover patent? A. Yes—it includes all of them. As long as they were in interference, it would include any application then in that interference —because the information would then have been available to all parties, and they could have had a chance to rebut it ex parte.

Judgment of Court of Appeals

No. 18,337

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

AMERICAN CYANAMID COMPANY, *Petitioner,* vs. FEDERAL TRADE COMMISSION, *Respondent.*	FILED SEPT. 30, 1968 CARL W. REUSS, Clerk ORDER

BEFORE: O'SULLIVAN, PHILLIPS and CELEBREZZE, Circuit Judges.

On petition to review and set aside an order of the Federal Trade Commission,

This cause came on to be heard on the transcript of the record from the Federal Trade Commission, and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the order of the Federal Trade Commission be and it is hereby affirmed and enforced.

No costs awarded. Rule 39(b).

Entered by order of the Court.

/s/ CARL W. REUSS
Clerk

Order of Court of Appeals Denying Petitions for Rehearing

Nos. 18,336-37

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

CHARLES PFIZER & CO., INC.,
Petitioner,
vs.
FEDERAL TRADE COMMISSION,
Respondent.

AMERICAN CYANAMID COMPANY,
Petitioner,
vs.
FEDERAL TRADE COMMISSION,
Respondent.

FILED
Nov. 8, 1968
CARL W. REUSS,
Clerk

ORDER

BEFORE: O'SULLIVAN, PHILLIPS and CELEBREZZE,
Circuit Judges.

Upon consideration, it is ORDERED that the petitions for rehearing of Charles Pfizer & Co., Inc. and American Cyanamid Company be and hereby are denied.

Entered by order of the Court.

/s/ CARL W. REUSS
Clerk